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PATENT
Box PCT
Attn: PCT Legal Office

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	
SABANATHAN, Thirumani	Examiner: Unassigned
Serial No. 09/762,692	Group Art Unit: Unassigned
Int. Filing Date: March 3, 1998	
Priority Date: April 30, 1997	
For: OCCLUSION DEVICE	Attorney Docket No.: 05424.00002

RENEWED PETITION UNDER 37 CFR 1.137(b) AND PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Applicant hereby requests reconsideration of the decision of the United States Patent and Trademark Office of May 24, 2001 to deny Applicant's first Petition for Revival of an Application for Patent Abandoned Unintentionally Under 37 CFR 1.137(b), filed February 9, 2001. Simultaneously, Applicant requests an extension of time of two months. Please charge our Deposit Account No. 19-0733 a fee of $195.00 for a two month extension by a small entity. It is believed that no fee is required for filing the renewed petition. If this fee calculation is incorrect, please charge the correct fee.

Basis for Renewed Petition

Applicant requests reconsideration on the basis that the facts before the PTO as provided in the first petition were incomplete, which apparently resulted in the false impression that the application had been intentionally abandoned on behalf of Applicant. Applicant asserts that the application was in fact unintentionally abandoned because: (1) Applicant did not intend to abandon the application; (2) Applicant is the rightful and sole owner of the application as determined by the UK Patent Office; (3) Applicant did not authorize any agent to abandon the application; (4) the agent who did abandon the application, Mr. Mark Lunt, was not acting on Applicant's behalf; and (5) in abandoning the application, Mr. Lunt acted on behalf of Bradford Hospital NHS Trust ("Bradford"), who at the time considered itself the owner of the application and controlled Mr. Lunt's actions.

Key to understanding the actions and intent of the parties associated with the subject application is the fact that Bradford had no ownership interest in the application. On January 21, 2001, just prior to Applicant's filing of the first petition to revive, the UK Patent Office concluded an entitlement proceeding which held that Applicant was the rightful and sole owner of the PCT application. This fact was not brought to the attention of the PTO in the first petition. At the time of abandonment, however, Bradford and Mr. Lunt regarded Bradford, not Applicant, as owner of the application. Mr. Lunt had previously obtained Applicant's signature on a power of attorney, in his view, as a mere formality required by U.S. law to file a PCT application designating the U.S. Thereafter, neither Mr. Lunt nor Bradford consulted with Applicant regarding any decision involved

in prosecuting or abandoning the application, completely disregarding Applicant's known wishes to fully prosecute the application.

Mr. Lunt abandoned the application in response to specific instructions from Bradford and without consulting Applicant, who only discovered the abandonment after the fact. Thus, the abandonment of the application by Mr. Lunt merely reflected the intention of a party who did not own the application. The abandonment by Mr. Lunt was unintentional with respect to Applicant, who was the actual owner. Mr. Lunt was not acting as Applicant's agent at the time of abandonment.

New declarations are hereby enclosed from Thirumani Sabanathan, the Applicant, and Mark Lunt, the European Patent Attorney who filed and abandoned the PCT application. These declarations are more factually complete than the declarations filed with the first petition. Twelve exhibits are enclosed which are referenced in the declaration of Mrs. Sabanathan and three further exhibits which are referenced in the declaration of Mark Lunt. For your convenience, a Table of Exhibits is also enclosed.

Summary of the Relevant Facts

The following key facts are established by the enclosed documents.

Mrs. Sabanathan was emotionally devastated by the unexpected death of her husband, the inventor, Sabaratnam Sabanathan. Mrs. Sabanathan regarded her late husband's patent application as his legacy. *See, e.g.*, Exhibit 5, wherein Susan Clark, Mrs. Sabanathan's solicitor, states: "Mrs. Sabanathan would however wish to see the title of the invention . . . bearing her husband's name . . . ." *See also* Exhibit 6, wherein

Ms. Clark states: ". . . the device itself will as far as it is within the Trust's power to procure, be known as 'Sabanathan's Lung Obdurator.'"

Ownership of the patent was disputed even before an application was filed. However, Bradford assumed the role as applicant, engaged Mr. Lunt as patent attorney, and took charge of prosecution. Prosecution began by filing a UK patent application on April 30, 1997. Bradford at first communicated with Mrs. Sabanathan only through a friend of her deceased husband, Dr. John Richardson. As a result of Dr. Richardson's intervention, an informal agreement was worked out, expressed in a letter of October 27, 1997 (Exhibit 4), whereby Bradford agreed to fund prosecution of the application in exchange for sharing royalties with Mrs. Sabanathan. Nothing in that agreement authorized Bradford to abandon the application.

Mrs. Sabanathan had no personal knowledge of patents and eventually obtained representation from a solicitor, Susan Clark, who was not a patent attorney. Mrs. Sabanathan insisted, through Ms. Clark, that Bradford keep her informed of the progress of prosecution, which Bradford failed to do. *See* Exhibit 5, wherein Ms. Clark states: "Mrs. Sabanathan is disappointed that no further consultation has taken place with her in relation to the British patent . . ." *See also* Exhibit 6: "The release to you of the Power of Attorney is obviously on the assumption that the agreement between the parties is as set out in the attached letter, that you keep us updated on a regular basis of the progress of the patents and any further development of the invention . . . ." S*ee also* Declaration of Thirumani Sabanathan, paragraph 9. Again, Mrs. Sabanathan did not authorize Bradford to abandon the application.

Mrs. Sabanathan signed a power of attorney (Exhibit 7) permitting Mark Lunt to file the PCT application. Mr. Lunt considered this a mere formality arising out of the U.S. requirement that the inventor sign as applicant. *See* Exhibit A, wherein Mr. Lunt states of the power of attorney: "It requires signature by Mrs. Sabanathan on the basis that she is an applicant for the invention for the United States, where it is a legal requirement that the applicant be the inventor or his heir if he is deceased." *See also* Declaration of Mark Lunt, paragraphs 6 and 8. Mr. Lunt believed that Bradford owned the invention and the application. *Id.*, paragraph 3. Mr. Lunt also considered Bradford as his client, not Mrs. Sabanathan. Mr. Lunt was paid by Bradford, carried out instructions given to him by Bradford, and never even spoke to Mrs. Sabanathan. *Id.*, paragraphs 8-10.

In October of 1999, as the deadline for filing a U.S. national phase application (October 30, 1999) was approaching, Bradford was contacted by Sally Whittle, who was Formalities Manager at Mr. Lunt's firm. *See* Exhibit B, letter of Sally Whittle to Dr. Dugdale dated October 4, 1999. A few days later Dr. Dugdale of Bradford instructed Mr. Lunt by telephone, and again by letter on October 8, 1999, not to proceed with the national phase filing. *See* Exhibit B. Mr. Lunt responded on October 14, 1999 that he would not take any action to keep the application alive. He stated, "We will not take any action positively to abandon them, in the unlikely event that the family of Dr. Sabanathan wants to take over the applications." *See* Exhibit B. However, Mr. Lunt did not inform Mrs. Sabanathan of the upcoming deadline. *See* Declaration of Mark Lunt, paragraph 9. Mrs. Sabanathan had no knowledge of the October 30, 1999 deadline for filing the U.S.

national phase application or that Mr. Lunt intended to allow that deadline to lapse on Bradford's behalf. *See* Declaration of Thirumani Sabanathan, paragraphs 12 and 13. Mrs. Sabanathan first learned of the deadline for filing the U.S. application in November of 1999 when she was contacted by Mr. Hanson Gifford, President of The Foundry LLC, who was seeking to acquire rights to the invention.

Relevant Case Law

Futures Technology Ltd. v. Quigg, 7 USPQ2d 1588 (E.D. Va 1988), is practically a blueprint for handling the present case. In *Futures Technology*, a patent application was abandoned by its legal owner contrary to a contractual agreement with the equitable owner. Due to an ongoing dispute between the legal and equitable owners of the application, the legal owner did not inform the equitable owner that it was allowing the patent to become abandoned. The court ruled that, under those circumstances, the application had been both unintentionally and unavoidably abandoned.

In the present case, Bradford has played a role which is higly analogous to that of the legal owner in *Futures Technology*, while Applicant's role is comparable to that of the equitable owner. The agreement between Bradford and Applicant required Bradford to fund and prosecute the application in exchange for a share of royalties; in *Futures Technology,* a contract required the legal owner to prosecute the application and share royalties with the equitable owner. Bradford's abandonment of the U.S. national phase application without informing Applicant is analogous to the abandonment by the legal owner in *Futures Technology* without informing the equitable owner. The court in

Futures Techonolgy held that the abandonment by the legal owner was unintentional (and even unavoidable) with respect to the equitable owner. And in this case, the abandonment by Bradford should be held to be unintentional with respect to Applicant.

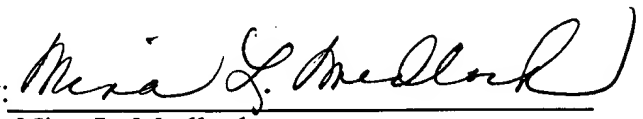
In re Application of G, 11 USPQ2d 1378 (Comm'r Pats. 1989), was cited as support for the PTO response to Applicant's first petition. However, that case was based on facts which are quite different from the present case. In *In re Application of G*, the application was abandoned because the applicant and the applicant's attorney could not distinguish over the cited prior art. The attorney allowed the application to become abandoned with the authorization of the applicant. Subsequent to abandonment, an approach was realized to distinguish the claimed invention from the prior art, and a petition was filed to revive the application based on unintentional abandonment. The court held that the act of abandonment had resulted from a deliberate decision on part of the applicant and the applicant's attorney, and therefore was intentional.

In the present case, however, no decision to abandon was made by Applicant or any authorized agent of Applicant. Mr. Lunt abandoned the application, acting on behalf of Bradford, contrary to the known desire of Applicant to prosecute the application, and without any consultation with Applicant.

For the above reasons, Applicant respectfully requests the revival and examination of the present application.

Respectfully submitted,

Date: September 24, 2001

By: 
Nina L. Medlock
Registration No. 29,673

Banner & Witcoff, Ltd.
1001 G Street, N.W., Eleventh Floor
Washington, D.C. 20001-4597
(202) 508-9100

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
SABANATHAN, Thirumani	)	Examiner: Unassigned
	)	
Serial No. 09/762,692	)	Group Art Unit: Unassigned
	)	
Int. Filing Date: March 3, 1998	)	
	)	
Priority Date: April 30, 1997	)	
	)	
For: OCCLUSION DEVICE	)	Attorney Docket No.: 05424.00002

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

EXCLUSIVE SUBSTITUTE POWER OF ATTORNEY AND EXCLUSIVE PROSECUTION HEREAFTER BY ASSIGNEE UNDER 37 C.F.R. §§ 1.36, 3.71 AND 3.73

The undersigned being the owner of all right, title and interest in the above-identified patent application, hereby revokes all previous powers of attorney in this case, if any, and hereby appoints the practitioners at Customer Number 22907 individually and collectively its attorneys to prosecute this application and to transact all business in the Patent and Trademark Office in connection therewith, and with the resulting patent.

I also authorize Banner & Witcoff, Ltd. to delete any attorney names/numbers no longer associated with Customer Number 22907 and to act and rely solely on instructions

communicated from the person, attorney, firm or other organization sending instructions to Banner & Witcoff, Ltd. on behalf of the owner.

Certificate Under 37 C.F.R. §3.73(b)

I hereby certify that Emphasys Medical, Inc. at 2686 Middlefield Road, Suite A, Redwood City, California 94063, is the assignee of the entire right, title and interest in the patent application identified above by virtue of an assignment from the inventor to the aforesaid assignee, a copy of the assignment being attached.

I have reviewed the documents in the chain of title of the patent application identified above, and to the best of my knowledge and belief, title is in the aforesaid assignee for which I am empowered to act in this matter.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

EMPHASYS MEDICAL, INC.

Date: 23 July 2001 By: _____

Name: Peter Chow
Title: Director, IP

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
SABANATHAN, Thirumani	)	Examiner: Unassigned
	)	
Serial No. 09/762,692	)	Group Art Unit: Unassigned
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Int. Filing Date: March 3, 1998	)	
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For: OCCLUSION DEVICE	)	Attorney Docket No.: 05424.00002

DECLARATION OF MARK LUNT
IN SUPPORT OF PETITION UNDER 37 CFR 1.137(b)

1. I, Mark Lunt, am a European Patent Attorney and a partner in the firm of Harrison Goddard Foote in the United Kingdom. Formerly, I was associated with the firm of Dibb Lupton Alsop, also in the United Kingdom.

2. In early 1997, I was contacted by Dr. Sabaratnam Sabanathan regarding his invention of a new lung treatment device. At the time Dr. Sabanathan was engaged as a part-time Consultant Cardiothoracic Surgeon with Bradford Hospitals NHS Trust ("Bradford").

3. Following the initial contact, I met with Dr. Sabanathan at the Bradford Royal Infirmary on March 4, 1997 and again on April 3, 1997. Subsequently, I was retained by Bradford to file a patent application in the United Kingdom, Application No. 9708681.3 ("the UK application") for the Sabanathan device. Based on my understanding that Dr. Sabanathan's research activity had been supported by Bradford and had taken place within the scope of his employment, I considered Bradford to be the owner of the invention and application.

4. I filed the UK application on April 30, 1997 and, in accordance with Bradford's instructions, named Dr. Sabanathan as the sole inventor. Bradford was the named applicant. Unbeknown to me at the time, Dr. Sabanathan had died suddenly on April 29, 1997.

5. On March 3, 1998, on Bradford's instructions, I filed an international application, International Patent Application No. PCT/GB98/00652 ("the PCT application"). The PCT application designated several countries for national phase filing, including the United States.

6. Prior to filing the PCT application, I forwarded two Powers of Attorney to Bradford for use in connection with the PCT application. The first required signature on

behalf of Bradford. I requested that Bradford obtain Mrs. Sabanathan's signature, as Dr. Sabanathan's heir, on the second Power of Attorney. It was my opinion that Mrs. Sabanathan's signature was required in order to designate the United States in the PCT application. (*See* Exhibit A, Letter dated February 17, 1998 from Mark Lunt to Dr. R.E. Dugdale). The PCT application also named Mrs. Sabanathan as the applicant for the U.S., which I understood was required under U.S. law. Bradford was named as the applicant for all other countries.

7. The deadline for filing a U.S. National Phase Application in this case was October 30, 1999. However, before that date, Bradford advised me that it had decided not to proceed with the PCT application. (*See* Exhibit B, Letters dated October 8, 1999 from Dr. Dugdale to Mark Lunt and October 14, 1999 from Mark Lunt to Dr. Dugdale). Accordingly, I allowed the PCT application to lapse without filing a U.S. National Phase Application.

8. Throughout the prosecution of the UK application and the PCT application, I regarded Bradford, not Mrs. Sabanathan, as my client, and I took instructions only from Bradford regarding prosecution of the applications. (*See* Exhibit C, Letters dated May 8, 1977 from Mark Lunt to Professor J. Richardson, May 18, 1997 from David Jackson to Mark Lunt, and June 4, 1997 from David Jackson to Mark Lunt). I also invoiced and forwarded all bills for my legal services to Bradford for payment. Though Mrs. Sabanathan had executed a Power of Attorney with respect to the PCT application, I considered that Power of Attorney a mere formality that would allow Bradford to file a patent application in the United States if Bradford chose to do so.

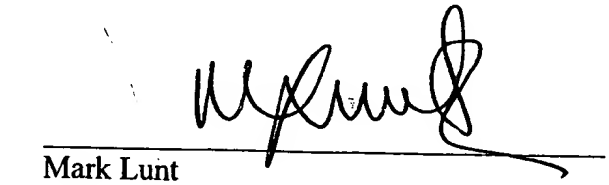
9. Following the filing of the PCT application, I had no further communication with Mrs. Sabanathan concerning prosecution of the patent applications. I never informed Mrs. Sabanathan of the progress of either the UK application or the PCT application. Nor did I advise Mrs. Sabanathan of Bradford's decision to allow the PCT application to lapse.

10. In allowing the PCT application to lapse, I acted on behalf of Bradford only, not Mrs. Sabanathan, and at Bradford's instruction.

11. I understand that willful false statements are punishable by fine or imprisonment or both under 18 U.S.C. § 1001 and may jeopardize the validity of the application or any patent issuing therefrom. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true.

MR

Date: 25 July 2001



Mark Lunt

Table of Exhibits

Exhibit	Description
1	GB app 9708681.3
2	PCT/GB/98/00652
3	EP app 98908220.1
4	Letter of David Jackson to Dr. John Richardson dated Oct 27, 1997
5	Letter of Susan Clark to Mr. Jackson dated March 31, 1998
6	Letter of Susan Clark to Dr. Dugdale dated March 31, 1998
7	Power of Attorney signed by Mrs. Sabanathan March 31, 1998
8	Agreement of Mrs. Sabanathan, Bradford Hospital, and The Foundry dated June 2000
9	Agreement of Mrs. Sabanathan and Bradford Hospital dated June 2000
10	Entitlement application submitted to UK Patent Office Sept 7, 2000 ("Statement of Case")
11	Entitlement decision of UK Patent Office dated Jan 21, 2001
12	*Greater Glasgow Health Board's Application* (key case in UK entitlement decision)
13	Letter of Mark Lunt to Dr. Dugdale dated Feb 17, 1998
14	Letter of Sally Whittle to Dr. Dugdale dated Oct 4, 1999
15	Letter of Dr. Dugdale to Mark Lunt dated Oct 8, 1999
16	Letter of Mark Lunt to Dr. Dugdale dated Oct 14, 1999

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

SABANATHAN, Thirumani

Serial No. 09/762,692

Int. Filing Date: March 3, 1998

Priority Date: April 30, 1997

For: OCCLUSION DEVICE

Examiner: Unassigned

Group Art Unit: Unassigned

Attorney Docket No.: 05424.00002

DECLARATION OF THIRUMANI SABANATHAN IN SUPPORT OF PETITION UNDER 37 CFR 1.137(b)

1. I, Thirumani Sabanathan, am the widow and heir of Dr. Sabaratnam Sabanathan. I have no formal training in law or medicine and no knowledge or experience relating to patents except through this case, as described below.

2. Dr. Sabaratnam Sabanathan, my deceased husband, was the inventor of a lung treatment device ("the Invention") which was the subject of United Kingdom Patent Application No. 9708681.3 ("the UK application"; Exhibit 1), International Patent Application No. PCT/GB98/00652 ("the PCT application"; Exhibit 2), and European Patent Application No. 98908220.1 ("the European application"; Exhibit 3). To the best of my knowledge, information, and belief my husband was the sole inventor with respect to those applications.

3. At the time Dr. Sabanathan developed the Invention, he was a part-time Consultant Cardiothoracic Surgeon with Bradford Hospitals NHS Trust ("Bradford") and additionally he was a cardiothoracic surgeon with his own private practice.

4. Bradford engaged a European Patent Attorney, Mr. Mark Lunt, to prepare the UK application.

5. Dr. Sabanathan died unexpectedly on April 29, 1997. The next day, Mr. Lunt filed the UK application which named Dr. Sabanathan as inventor and Bradford as applicant.

6. Following Dr. Sabanathan's death, I met with Dr. John Richardson, who was a Consultant Anaesthetist at Bradford and had been a friend and colleague of Dr. Sabanathan. Dr. Richardson negotiated on my behalf with Bradford regarding my interest in prosecuting the patent and preserving Dr. Sabanathan's legacy.

7. As a result of Dr. Richardson's negotiations, Bradford, through its chief executive Mr. David Jackson, offered to pay for the expenses of prosecuting the patent applications, including paying the fees of Mr. Lunt. Mr. Jackson formalized Bradford's pledge in a letter of October 27, 1997 (Exhibit 4).

8. In March of 1998 I again met with Dr. Richardson, who brought me a power of attorney to sign so that Bradford and Mr. Lunt could file the PCT application. At that time I engaged solicitor Susan Clark to further negotiate with Bradford on my behalf.

9. Ms. Clark wrote to Mr. Jackson on March 31, 1998 (Exhibit 5) to obtain his assurance that, if I cooperated with any patent application, then Bradford would pay for prosecuting the PCT application, including Mr. Lunt's fees, and in the event the invention was commercialized that I would share royalties equally with Bradford, after prosecution expenses were subtracted. Ms. Clark then wrote to Dr Dugdale on 31 March 1998 (Exhibit 6) to obtain Bradford's assurance that if we handed over the power of attorney I would be kept informed of the progress of prosecuting the patent applications.

10. Although Dr. Sabanathan was the inventor, I felt it was appropriate that Bradford pay the prosecution costs for the patent applications. My principal concern was to preserve Dr. Sabanathan's legacy as the inventor.

11. I signed a Power of Attorney (Exhibit 7) on March 31, 1998 in Ms. Clark's office. I understood that without my signing the Power of Attorney, no patent application could be filed in the United States.

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12. After the signing of the Power of Attorney in April of 1998, I received no communications whatsoever concerning the prosecution of the patent applications from either Bradford or Mr. Lunt, throughout the prosecution of the PCT application during 1998 and 1999. Before the application lapsed, neither I nor Susan Clark was aware that Bradford had decided to let the application lapse.

April 1998 through Feb 2000

13. I first learned that the PCT application had lapsed when Mr. Hanson Gifford, President of The Foundry LLC of Redwood City, CA, contacted me in February 2000. The Foundry was interested in acquiring the rights to the patent applications and the invention.

14. After three-way negotiations between myself, Bradford, and The Foundry, I signed one agreement with Bradford and a second agreement with Bradford and the Foundry. Both agreements were executed in June of 2000.

15. In the first agreement (Exhibit 8), the parties continued their agreement to share royalties. I promised to file an entitlement application with the UK Patent Office, and Bradford agreed not to contest the application. Both parties were willing to rely on the determination of the UK Patent Office.

16. In the second agreement (Exhibit 9), Bradford and I agreed to assign any rights we might have in the patent applications to The Foundry in exchange for each receiving a cash payment and a share of any eventual royalties from commercialization of the Invention.

17. On September 7, 2000 an entitlement application (Exhibit 10) was filed in the UK Patent Office on my behalf. I claimed ownership of the patent applications because Dr. Sabanathan was the sole inventor, and he developed the Invention independently of his part-time work at Bradford.

18. On January 21, 2001, the UK Patent Office awarded title to the patent applications to me. In its entitlement decision (Exhibit 11), the UK Patent Office referred to a case (*Greater Glasgow Health Board's Application*, Exhibit 12) holding that a medical doctor employed to work part time by a hospital and not required to do research was entitled to ownership of an invention he had made.

19. Because I am the true owner of the PCT application, and because Mr. Lunt did not act on my behalf in allowing the PCT application to lapse, I hereby petition for late entry into the U.S. national phase.

20. I, Thirumani Sabanathan, understand that willful false statements are punishable by fine or imprisonment or both under 18 U.S.C. § 1001 and may jeopardize the validity of the application or any patent issuing therefrom. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true.

Date: 20/7/01

T Sabanathan .

Thirumani Sabanathan

Table of Exhibits

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1	GB app 9708681.3
2	PCT/GB/98/00652
3	EP app 98908220.1
4	Letter of David Jackson to Dr. John Richardson dated Oct 27, 1997
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A	Letter of Mark Lunt to Dr. R.E. Dugdale dated Feb 17, 1998
B	Letter of Sally Whittle to Dr. R.E. Dugdale dated Oct 4, 1999; Letter of Dr. R.E. Dugdale to Mark Lunt dated Oct 8, 1999; and Letter of Mark Lunt to Dr. R.E. Dugdale dated Oct 14, 1999
C	Letter of Mark Lunt to Dr. John Richardson dated May 8, 1997; Letter of David Jackson to Mark Lunt dated May 18, 1997; and Letter of David Jackson to Mark Lunt dated June 4, 1997

(12) UK Patent Application (19) GB (11) 2 324 729 (13) A

(43) Date of A Publication 04.11.1998

(21) Application No 9708681.3

(22) Date of Filing 30.04.1997

(51) INT CL[6]
A61B 17/12

(52) UK CL (Edition P)
A5R RAM

(56) Documents Cited
WO 95/32018 A1 US 5588424 A US 5382261 A

(58) Field of Search
UK CL (Edition O) A5R RAM RAP REYX
INT CL[6] A61B 17/12 17/24, A61F 2/04
Online: WPI, MEDLINE

(71) Applicant(s)
Bradford Hospitals NHS Trust
(Incorporated in the United Kingdom)
Duckworth Lane, BRADFORD, West Yorkshire,
BD9 6RJ, United Kingdom

(72) Inventor(s)
Sabaratnam Sabanathan

(74) Agent and/or Address for Service
Dibb Lupton Alsop
Fountain Precinct, Balm Green, SHEFFIELD, S1 1RZ,
United Kingdom

(54) Abstract Title
Lung treatment device

(57) An obturator for a bronchial tube or tubule of a human or animal lung comprises a blocking element (92) and a securing element (90). The blocking element serves to seal the tube or tubule against the passage of fluid past the obturator when the obturator is disposed in a bronchial tube or tubule. The securing element serves to retain the blocking element in position. The blocking element comprises a substantially cylindrical plug of biocompatible, resiliently deformable closed-cell foamed plastics material, such as PVC. The securing element comprises a stent having barbs (98) to engage and retain the blocking element. The stent also has anchors (100) to retain the stent in a bronchial tube or tubule. A delivery device for the obturator is also disclosed.

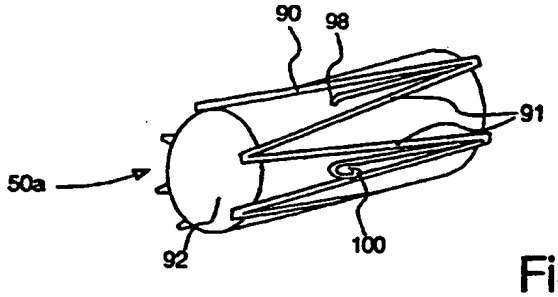

Fig. 3a

GB 2 324 729 A

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

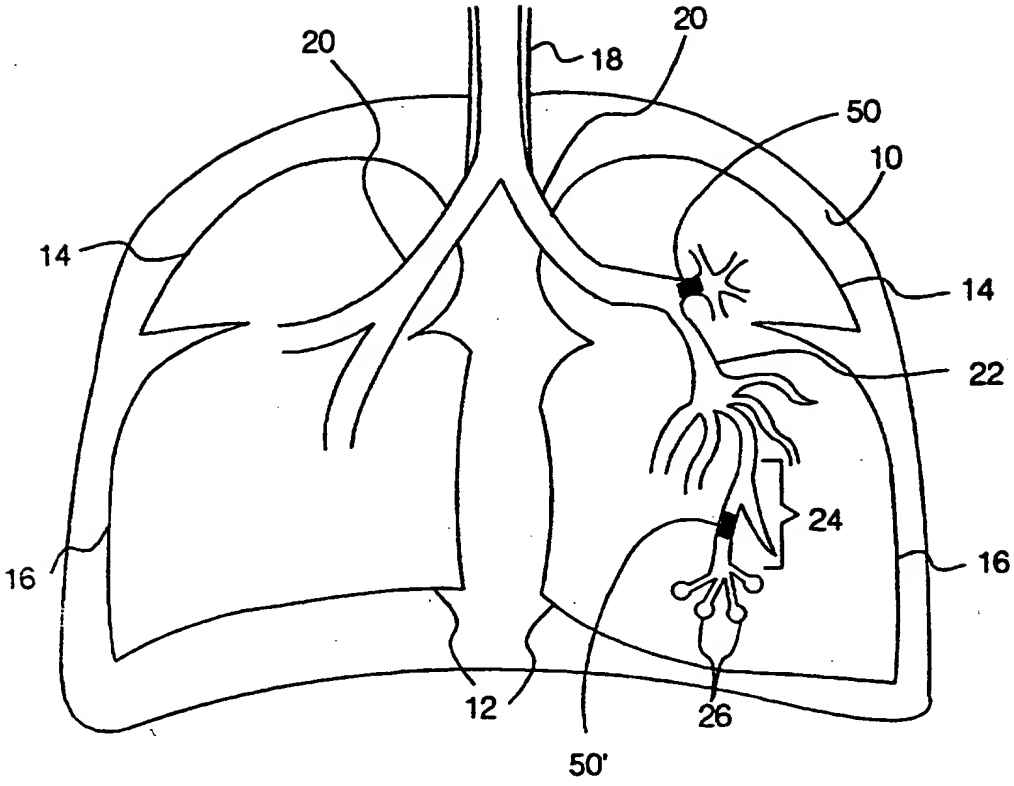

Fig. 1

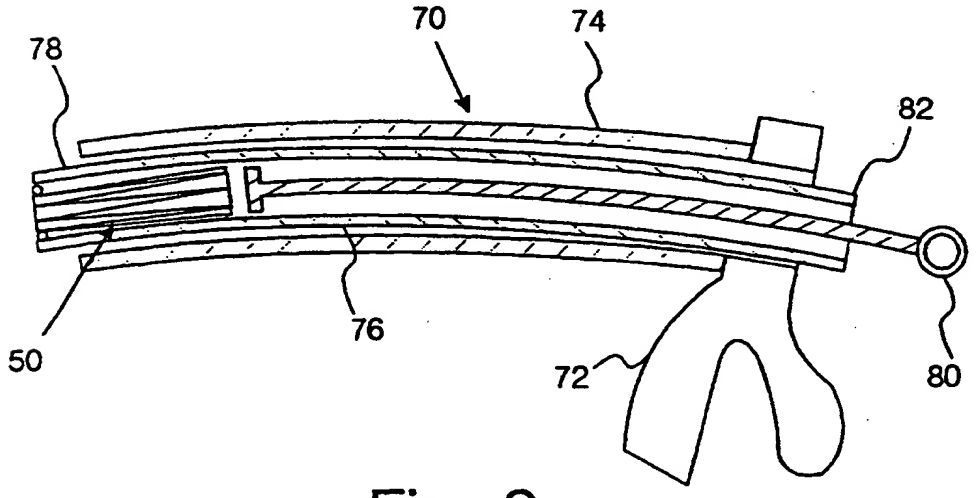

Fig. 2

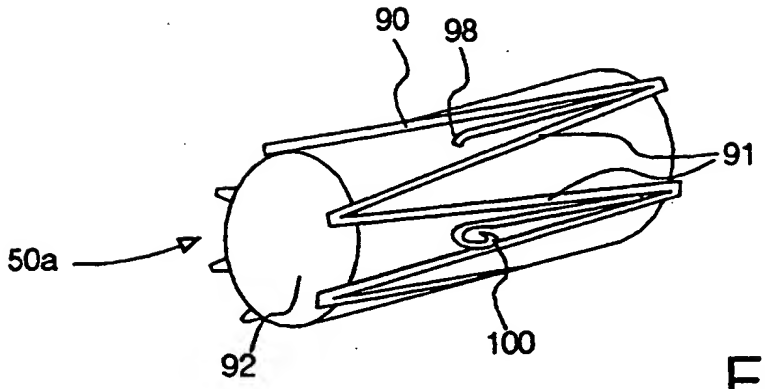

Fig. 3a

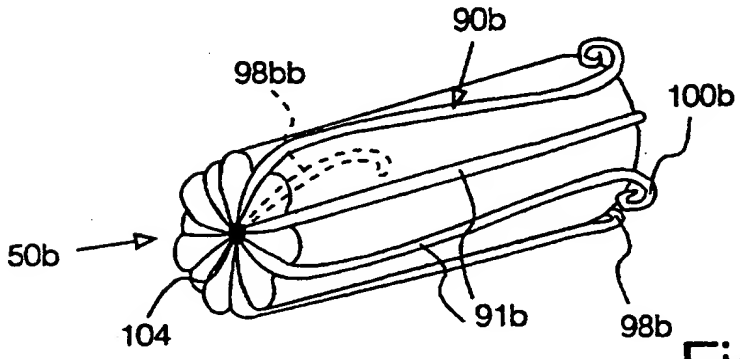

Fig. 3b

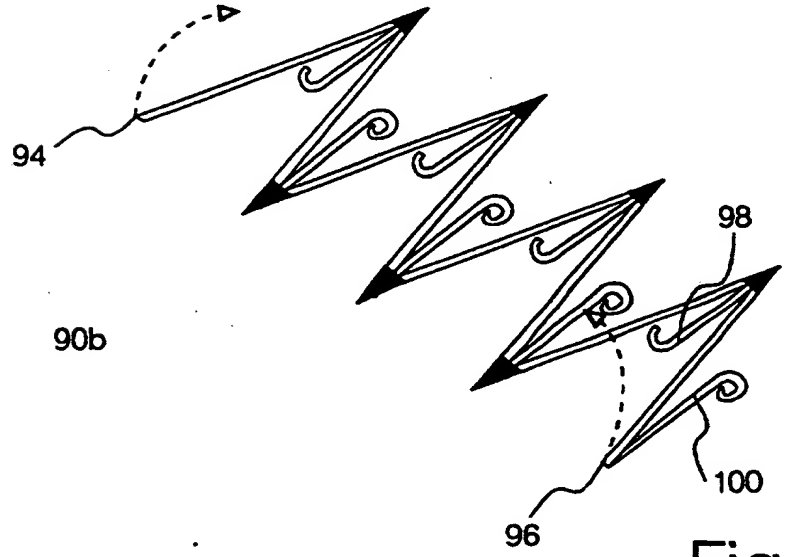

Fig. 3c

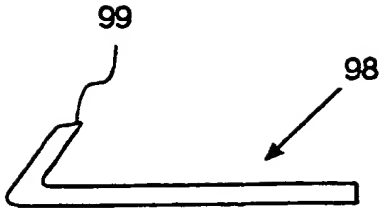

Fig. 4a

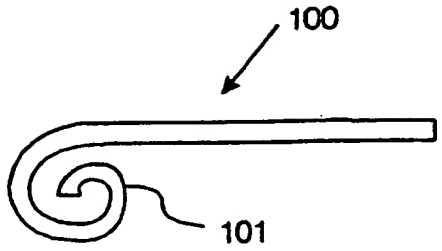

Fig. 4b

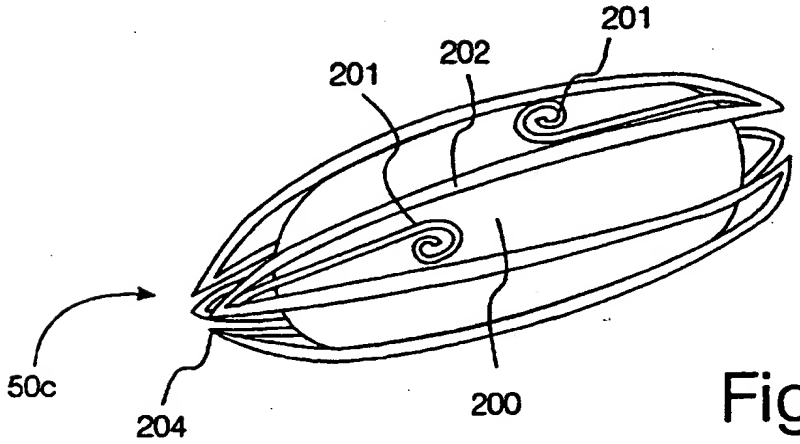

Fig. 5

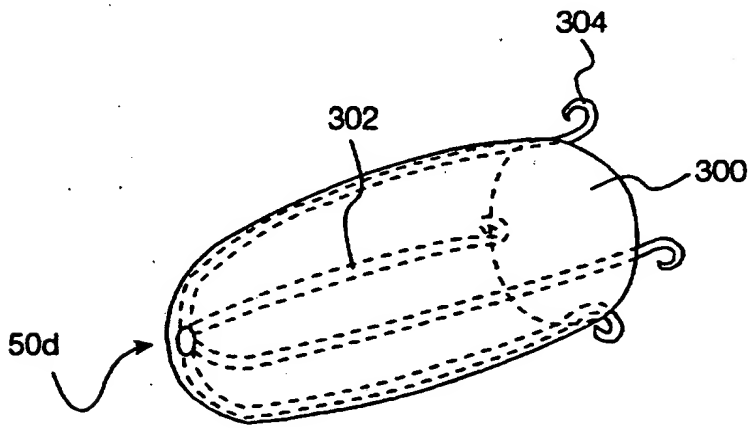

Fig. 6

Lung Treatment Device

The present invention relates to a device useful in the treatment of emphysema and other diseases or disorders of the human or animal lung.

Emphysema is a disease of the lung caused primarily by prolonged smoking, although not exclusively thereby. It is an unrelentless, intractable and debilitating process. Emphysema is defined as an abnormal permanent enlargement of the air spaces distal to the terminal bronchioles, accompanied by destruction of their walls without obvious fibrosis. In this context, destruction means non-uniformity in the pattern of respiratory airspace enlargement; orderly appearance of the acinus is disturbed and may be lost.

Emphysema causes a physiological loss of lung elastic recoil, which decreases expiratory airflow by loss of driving pressure and premature airway closure from reduced airway traction. The effect of this is that the alveoli become hyper-inflated without there being any real exchange of air with the outside. Therefore the patient begins to feel starved of oxygen and so attempts

to breathe more deeply. In breathing more deeply, the effects are exacerbated.

Not only are those individual alveoli which have a block in their respective bronchial tubules affected, but also neighbouring alveoli, perhaps in other regions of the lung, which may otherwise be perfectly serviceable, become affected because the hyper-inflated alveoli pressurise neighbouring alveoli and prevent them from expanding fully. There is, of course, a relatively fixed "exchange" volume of an individual's lung, that is to say, the difference between the expanded volume and the deflated volume. Emphysema reduces the exchange volume because undeflated alveoli occupy that space. Consequently, the only recourse available to the patient is to increase the expanded volume, thereby resulting in the barrel chest symptomatic of emphysema sufferers.

The major therapeutic modalities currently available consist of bronchodilator and anti-inflammatory drugs, directed at decreasing airway resistance, and antibiotics to treat acute and chronic infection. Supplemental oxygen therapy for the hypoxaemic patient improves exercise performance and improves survival in patients with cor pulmonale. Despite all available medical therapies, the course of the disease is one of

progressive limitation, increasing dyspnoea and significant increase in overall mortality.

It has long been realised that full lung volume is more than enough for survival in most circumstances and that a person can survive quite satisfactorily with only one lung, for example. Heterogenous distribution of emphysema, together with the lack of pulmonary blood flow to those areas have made lung volume reduction surgery a logical option. Removal of parts of the lung affected by emphysema permits unaffected areas to become operative again and so enable a better quality of life for the patient. Clearly, however, such invasive procedures are of a very serious nature and some patients will not, in any event, be in a sufficiently strong condition to accept the trauma of such procedures. Primarily, the basic relief for emphysema sufferers is inactivity, on the one hand, and breathing pure oxygen, on the other.

Emphysema is a distressing condition affecting a relatively large proportion of the population, and a more effective and less traumatic treatment is required.

On a different matter, other lung conditions sometimes lead to bleeding into the lung. A patient having this condition feels movement of the blood caused by airflow in the lung during breathing, and perceives the blood as

a foreign body and irritant. The patient coughs in an attempt to dislodge the perceived foreign body. Coughing blood, of course, is sometimes the first warning of a more serious disease or condition, but once that is realised, there is no benefit in such bleeding. Moreover, in such conditions where the lung might heal itself and subsequently stop bleeding, or indeed simply where the bleeding needs to be confined, the coughing reaction, which is almost impossible to resist, does not help the situation at all, and merely spreads the blood to other areas of the lung.

Therefore it is an object of the present invention to provide a method of treatment of certain lung conditions or diseases and to provide a device for such treatment.

In accordance with a first aspect of the present invention there is provided a method of treatment of emphysema or other lung conditions or diseases, the method comprising placing an obturator in a bronchial tube or tubule so as to seal the tube or tubule against the passage of fluid past the obturator.

In the case of emphysema, and by the simple expedient of inserting an obturator in a bronchial tube, a section of a lung can be isolated so that no air can be drawn into it. Thereafter, the isolated part deflates in time as the

air remaining in it becomes absorbed, and so that part of the lung stops affecting other areas of the lungs, which can thus perform normally. Such a procedure is relatively simple, requiring only a delivery device for the obturator, which device is inserted through the mouth and airway of the patient until the proposed placement site is reached, whereupon the device is activated to release the obturator from the device.

In the case of bleeding into the lung, an obturator stops the flow of blood. The lung is tamponated by the obturator and blood merely collects in the isolated part of the lung and ultimately, if the bleeding stops, will be reabsorbed. Alternatively, in the case of some, perhaps terminal, conditions such as some lung cancers, it at least provides temporary relief for the patient.

In accordance with a second aspect of the invention there is provided an obturator for a bronchial tube or tubule of a human or animal lung comprising a blocking element and a securing element.

Preferably the two elements are separate components, the blocking element serving to seal the tube or tubule against the passage of fluid past the obturator when the obturator is disposed in a bronchial tube or tubule, and

the securing element serving to retain the blocking element in position in the tube or tubule.

The blocking element preferably comprises a substantially cylindrical plug of biocompatible material. The plug may comprise resiliently deformable closed-cell foamed plastics material, such as PVC, so that it may be compressed to facilitate insertion into the tube or tubule and thereafter expand to fill the cross-section of the tube or tubule.

It is known to employ stents in medical fields to expand and support collapsed blood vessels, and indeed bronchial tubes. A stent is a compressible framework which, when inserted into a vessel and released, expands and, within the limits of its expansion, supports and possibly expands the walls of the vessel.

Preferably, the securing element comprises a stent. The stent may have barbs to engage and retain the blocking element. The stent preferably also has anchors to retain the stent in a bronchial tube or tubule.

In one embodiment, the stent comprises a crown of surgical quality steel wire legs in zig-zag formation. Said barbs and anchors may depend from points of the

crown. Preferably the crown is closed in its circumference, although this is not essential.

In another embodiment, the stent comprises a dome of surgical quality steel wire legs. Said barbs and anchors may be formed on the ends of said legs.

It is known in medical fields to block blood vessels, for example where a genetic or other defect has resulted in a hole which needs blocking, or, for example, in the case of babies whose aortic to pulmonary artery connection has not closed following birth, a condition known as patent ductus arteriosus. In the case of holes, it is well known to employ an "umbrella", where a diaphragm of material forms the seal against the blood vessel wall, the handle of the umbrella serving to keep the diaphragm across the vessel. In the case of babies, it has also been known to employ a plug of PVC foam to treat patent ductus arteriosus, the plug encouraging clotting.

However, in the case of bronchial tubes and tubules a diaphragm seal is not been used yet, although its application cannot be entirely ruled out. For example, an umbrella device with a larger surface area of contact with the bronchial mucosa might be as effective.

In blood vessels a complete seal is seldom required because any leak soon blocks by the formation of a clot; something that would not happen in an airway of a lung. Secondly, airways are not always absolutely circular in section, so a circular diaphragm may not always make a good seal, at least around some parts of the circumference, unless it has capacity to expand in all radial directions and has a large contact area.

However, a complete seal is an absolute requirement of the present invention (at least over the period of a single breath), because without it, air can leak past during inhalation and pressurise the lung in just the same way, and perhaps even to a greater extent. More importantly, however, a patient with such an obturator in place can only feel its presence if there is movement of air around it to stimulate adjacent nerve endings. Once a patient can feel the obturator, there will be irresistible compulsion to cough which, if done excessively, may be sufficient to dislodge the obturator.

Thus it has been found that a very effective seal is achieved by the use of said cylindrical plug of foamed PVC (of the type commonly employed as earplugs). The effectiveness of this arrangement is probably due to the fact that any leakage path has to be a long one and there are thus numerous opportunities for it to close and seal

about at least one closed circuit around the plug. Another reason is that a plug can mould itself to the shape of the tube or tubule, which is itself unlikely to be cylindrical, or, indeed, circular in cross-section.

Preferably, the method of the present invention employs an obturator of the type defined above.

The delivery device preferably comprises a delivery tube in which the obturator is received in a compressed state at a distal end thereof, a guide tube, which is capable of following a possibly tortuous path under the guidance of a surgeon from entry into the mouth of a patient, down the patient's trachea and one bronchus to a proposed delivery site in a bronchial tube or tubule, and which has a passage to receive the delivery tube therealong, and release means to eject the obturator from the delivery tube and guide tube.

The obturator needs to slide in the delivery tube during ejection and the stent provides a low friction surface of the obturator to facilitate such ejection.

It is feasible that the blocking and securing elements may be integrally formed from plastics material, and wherein the securing element comprises adhered or fused anchor elements on the blocking element.

It is also feasible that the securing element may comprise a memory metal which is released to its normal expanded shape by a physical parameter, for example, the passage of an electric current therethrough, once it has been inserted at the proposed location. Otherwise it is in the same form as the above described steel stent which relies on resilience for its expansion. The advantage of a memory metal device is that it requires no compression during insertion so that the delivery tube of the delivery device may be replaced by a simple guide rod to which it is connected.

The invention will be better understood from the following description of particular embodiments given as non-limiting examples. The description refers to the accompanying drawings, in which :-

Figure 1 shows a section through the human chest indicating the location of bronchial obturators in the lungs;

Figure 2 shows a bronchial obturator complete with delivery system;

Figures 3a b and c show in perspective two embodiments of an obturator according to the present invention, that of Figure 3a having a crown stent, and that of Figure 3b having a dome stent, Figure 3c being a

crown stent in an open configuration prior to rolling and, optionally, welding into a ring as in Figure 3a;

Figures 4a and b show an internal barb and external anchor respectively;

Figure 5 is a perspective view of another embodiment of obturator in accordance with the present invention; and,

Figure 6 is a perspective view of yet another embodiment of obturator also in accordance with the present invention.

In Figure 1 of the drawings, a human chest cavity 10 includes a pair of lungs 12 which each comprise upper and lower lobes 14,16. A trachea 18 branches into two bronchi 20, which further branch into bronchial tubes 22 and segmental bronchi 24. The bronchi 24, after further branching, terminate in alveoli 26.

In the majority of patients suffering from emphysema, it frequently effects mainly the upper lobes 14 of the lungs, leaving the lower lobes 16 unaffected, or at least less affected. However, if no treatment is given to a patient, the expansion effect of the upper lobes as the condition develops presses on the lower lobes and reduces their capacity to perform efficiently. Lower lobe emphysema does occur in some patients, and in which event it is then the upper lobes which are compressed.

Thus the present invention suggests placing an obturator 50 in a bronchial tube or tubule to isolate the region of the lung supplied by that tube or tubule. Where the obturator is placed will be decided by the surgeon and will depend on the how localised the damaged region of lung is. That is to say, if the whole lobe is badly affected, then the obturator is placed in the lobar bronchus 22 supplying that lobe (as shown at 50 in Figure 1). On the other hand, if the damage is more localised, then the obturator will be placed in a smaller segmental bronchus 24, (as shown at 50' in Figure 1). Thus more than one obturator may be employed in the same pair of lungs isolating different regions of them. They will also be of different sizes, depending where they are to be inserted.

The above considerations equally apply when the condition being treated is not emphysema but some other condition which a doctor considers can usefully be treated by the method of the present invention. Such another condition is where a lung, or part of it is bleeding into the airway and an obturator isolates the bleeding region and inhibits coughing which may damage the lung further, or at least cause further discomfort to the patient.

Figure 2 shows an endo-bronchial obturator 50 complete with delivery device 70. The delivery device comprises a

handle 72 and flexible guide tube 74. Slidably received in the guide tube is a delivery tube 76 having the obturator 50 disposed at its distal end 78. A release means 80 is insertable in a proximal end 82 of the delivery tube 82 and by means of which the obturator 50 may be ejected from the end of the delivery tube. The guide tube is guided down the trachea and into the appropriate bronchus by means of guide lines (not shown) which enable the delivery system to be turned to follow the desired course. Optical guidance means may be included, or real-time X-ray or other monitoring methods may be employed to guide the surgeon. Once the end of the guide tube reaches the correct location, the delivery tube is inserted in the handle end of the delivery device 70, and then the release means 80 is pushed down the tube 82 to eject the obturator. The obturator is adapted to expand or be expanded, when ejected, to fill and block the tube or tubule in which it is inserted.

As can be seen from Figure 3a, the obturator 50 in its first embodiment is comprised of two main components, a securing element in the form of a stent 90, and a blocking element in the form of a closed-cell, PVC foam plug 92.

The stent 90 is constructed from a plurality of legs 91 of surgical grade stainless steel wire welded together

such that when extended the stent appears as a series of connected 'W's, as shown in an unconnected disposition in Figure 3c. Indeed, it is not essential that the final connection between ends 94,96 be made to form a closed crown arrangement (as shown in Figure 3a); it is equally effective merely to roll the stent 90b as indicated by arrows in Figure 3c.

When the two ends of the stent are joined together, the stent 90 folds into a circular frame or crown, capable of encompassing the biocompatible block 92. The stent is constructed so as to be of a size slightly smaller (in its unstressed condition) than the block, so that its natural resilience squeezes the block slightly. On the other hand, the stent should be larger than the airway into which it is to be introduced so that it presses outwardly against the wall of the airway, and is incorporated into the mucosa of the air passage.

The legs 91 of the stent crown are fitted with both internal barbs 98 and external anchors 100. The barbs 98 embed themselves in the block 92 and secure the block to the stent 90. The anchors 100 are adapted to engage the walls of the patient's airways to hold the stent in position.

Figure 4a shows an internal barb 98. The internal barb, also constructed from surgical quality stainless steel, is substantially straight and has a hook 99 at one end. The hooked end 99 is the point and means by which the barb is secured to the biocompatible block.

Figure 4b shows an external anchor 100. The anchor, which is also constructed from surgical quality stainless steel, is again substantially straight and has a coil 101 at its end. A coil is used so that damage is not caused to the tissue of the airway in which the obturator is fitted, particularly if and when the obturator is removed.

The barbs and anchors are joined to the stent crown by a welded joint between two adjacent legs 91. Barbs can alternate with anchors at the same end of the stent, or one end can have all barbs, while the other end has all anchors. Both arrangements are shown in Figures 3a and c respectively.

A different embodiment of obturator 50b, also in accordance with the present invention, is shown in Figure 3b in which surgical quality stainless steel wires are all welded together at a point 104 to form a domed stent 90b. Legs 91b are alternately turned inwards to form barbs 98b, or outwards to form anchors 100b.

Alternatively, all the legs could be anchors 100b, with interspersed shorter barbs 98bb, as one is shown in dashed lines in Figure 3b.

The aforementioned obturators all rely on resilience of the steel to return the stent to its original shape once released from the delivery mechanism and so as to enable fitment in a narrower tubule than the unstressed size of the stent would otherwise allow. However, this requires prestressing the stent and keeping it stressed during delivery. Thus the present invention may find suitable application for memory metals, which only return to their original shape when some physical condition changes, for example, temperature rise or electrical current flow.

It is essential for the blocking device 50 to be comprised of a resiliently deformable material such as PVC foam as mentioned above. This enables the blocking device to be easily surrounded by the stent 90 and deformed into a compact structure, thereby enabling delivery of the block to its destination in the lung.

It is likewise essential that the block be capable of expanding and reforming into its original shape once deposited in the desired location in the lungs. It should be noted that the block is deformed and reformed in both an axial and a radial direction. It is the block 92

which seals a bronchial tube or tubule; mucous surrounds the block and forms a fluid tight seal. The presence of the stent around the block does not inhibit sealing in any way since the stent is essentially incorporated into the mucosa lining the airway.

Under compression, PVC foam has a high coefficient of friction which would prevent ejection from the delivery device as described above, if it was not surrounded by the stent 90, which offers a relatively low friction surface to the inside of delivery tube 76.

However, it is feasible that the block 92 could include a low friction surface to enable such ejection without the stent. Instead of the stent as described above, anchor means might be moulded in biocompatible plastics material as a crown, for example, on one end of the block, and either be adhered, fused or otherwise bound thereto.

The effectiveness of the device depends, to some extent, on the length of the block. Moreover, the block is required to be of a size which is both comfortable to the patient once expanded in the lung and which expands to completely obstruct the passage of air into the affected portions of the lung. The extended size of the block therefore ranges between 5mm and 25mm in length, and

between 5 and 11mm in diameter, depending on the size of the tube or tubule to be obturated.

Obturator 50c shown in Figure 5, comprises a balloon 200, which is inflated after insertion and then detached. The balloon is captivated in an appropriate securing device such as stent 202. In this case, the barbs would not be sharp, but would merely retain ends of the balloon, or, as shown, would comprises turned-in points 204,206 at each end of the stent.

Finally, as mentioned above, the obturator may be as shown at 50d in Figure 6, where it comprises a diaphragm 300 expanded by an internal stent 302 having anchors 302. One end 306 of the diaphragm is attached to the stent to retain it on the stent. The diaphragm is also adhered to the stent.

While the obturator and method of the present invention has been described with reference to human patients, animal patients may in certain circumstances also benefit.

The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and which are open to public inspection with this

specification, and the contents of all such papers and documents are incorporated herein by reference.

All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

Each feature disclosed in this specification (including any accompanying claims, abstract and drawings), may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each feature disclosed is one example only of a generic series of equivalent or similar features.

The invention is not restricted to the details of the foregoing embodiments. The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

CLAIMS

1. An obturator for a bronchial tube or tubule of a human or animal lung comprising a blocking element and a securing element.

2. An obturator as claimed in claim 1, in which the two elements are separate components, the blocking element serving to seal the tube or tubule against the passage of fluid past the obturator when the obturator is disposed in a bronchial tube or tubule, and the securing element serving to retain the blocking element in position in the tube or tubule.

3. An obturator as claimed in claim 1 or 2, in which the blocking element comprises a substantially cylindrical plug of biocompatible material.

4. An obturator as claimed in claim 3, in which the plug comprises resiliently deformable closed-cell foamed plastics material, such as PVC.

5. An obturator as claimed in any preceding claim, in which the securing element comprises a stent.

6. An obturator as claimed in claim 5, in which the stent has barbs to engage and retain the blocking element.

7. An obturator as claimed in claim 5 or 6, in which the stent has anchors to retain the stent in a bronchial tube or tubule.

8. An obturator as claimed in claim 5, 6 or 7, in which the stent comprises a crown of surgical quality steel wire legs in zig-zag formation.

9. An obturator as claimed in claims 6, 7 and 8, in which said barbs and anchors depend from points of the crown.

10. An obturator as claimed in claim 8 or 9, in which the crown is closed in its circumference.

11. An obturator as claimed in claim 5, 6 or 7, in which the stent comprises a dome of surgical quality steel wire legs.

12. An obturator as claimed in claim 11, when dependent on claim 6, in which said barbs are formed on the ends of said legs.

13. An obturator as claimed in claim 11 or 12, when dependent on claim 7, in which said anchors are formed on the end of said legs.

14. An obturator as claimed in any preceding claim, further comprising a delivery device, which device comprises a delivery tube in which the obturator is received in a compressed state at a distal end thereof, a guide tube, which is capable of following a path under the guidance of a surgeon to a proposed delivery site in a bronchial tube or tubule, and which has a passage to receive the delivery tube therealong, and release means to eject the obturator from the delivery tube and guide tube.

15. An obturator as claimed in claim 14, when dependent on claim 5, in which the stent provides a low friction surface of the obturator to facilitate such ejection.

16. An obturator as claimed in claim 1, in which the blocking and securing elements are integrally formed from plastics material, and wherein the securing element comprises adhered or fused anchor elements on the blocking element.

17. An obturator as claimed in claim 2, in which the securing element comprises a memory metal which is

released to its normal expanded shape by a physical parameter when it has been inserted at the proposed location.

18. An obturator as claimed in claim 17, in which said physical parameter is the passage of electrical current through the securing means.

19. An obturator as claimed in claim 1 or 2, in which the blocking element comprises a balloon.

20. An obturator as claimed in claim 19, in which the securing element comprises a stent, points of the stent being turned inwardly to captivate the balloon.

21. An obturator as claimed in claim 1 or 2, in which the blocking element comprises a diaphragm.

22. An obturator as claimed in claim 21, in which the securing element comprises a domed stent secured at its point to the centre of the diaphragm, the legs of the stent pressing the diaphragm against the mucosa of a bronchial tube when inserted therein.

23. A method of treatment of emphysema or other lung conditions or diseases in human or animal patients, the method comprising placing an obturator in a bronchial

tube or tubule of the patient so as to seal the tube or tubule against the passage of fluid past the obturator.

24. A method as claimed in claim 23, in which the obturator is put in place in a patient by use of a delivery device for the obturator, which device is inserted through the mouth and airway of the patient until the proposed placement site is reached, whereupon the device is activated to release the obturator from the device.

25. A method as claimed in claim 23 or 24, which method employs an obturator of the type claimed in any of claims 1 to 22.

26. An obturator substantially as hereinbefore described with reference to any of the accompanying drawings.

The Patent Office

25

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Claims searched:	1-22 and 26	**Date of search:**	2 September 1997

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Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5R (REYX, RAP, RAM)

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Other: Online: WPI, MEDLINE

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
Y	WO 95/32018 A1	(TEIRSTEIN) see page 1 lines 7-9, page 4 line 15 - page 7 line 19 and page 11 line 35 - page 12 line 7.	1, 2, 5, 7, 19 and 21
Y	US 5588424	(INSLER) see whole document.	1, 2, 5, 7, 19 and 21
Y	US 5382261	(PALMAZ) see column 4 line 4 - column 6 line 2.	1, 2, 5 and 21

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
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(71) Applicant *(for all designated States except US)*: BRADFORD HOSPITALS NHS TRUST [GB/GB]; Duckworth Lane, Bradford, West Yorkshire BD9 6RY (GB).

(71) Applicant *(for US only)*: SABANATHAN, Thirumani (heir of the deceased inventor) [GB/GB]; 8 Foster Park Road, Denholme, Bradford BD13 4BE (GB).

(72) Inventor: SABANATHAN, Sabaratnam (deceased).

(74) Agent: LUNT, Mark, George, Francis; Dibb Lupton Alsop, Fountain Precinct, Balm Green, Sheffield S1 1RZ (GB).

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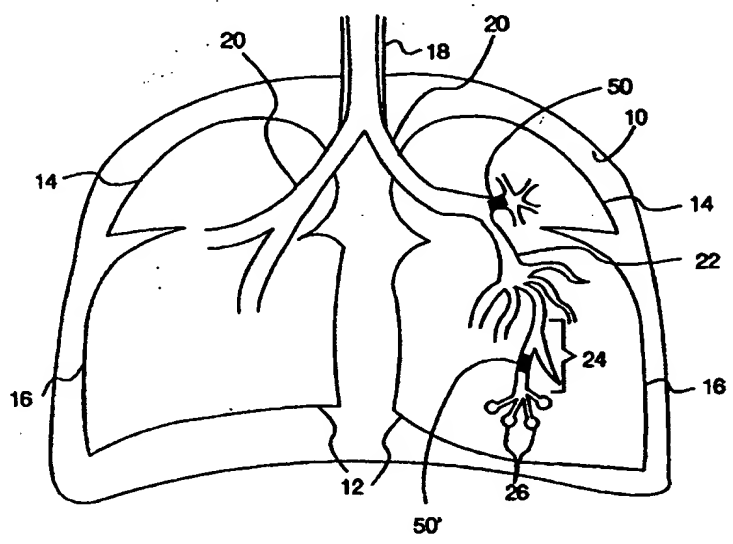

(57) Abstract

An obturator for a bronchial tube or tubule of a human or animal lung comprises a blocking element (92) and a securing element (90). The blocking element serves to seal the tube or tubule against the passage of fluid past the obturator when the obturator is disposed in a bronchial tube or tubule. The securing element serves to retain the blocking element in position. The blocking element comprises a substantially cylindrical plug of biocompatible, resiliently deformable closed-cell foamed plastics material, such as PVC. The securing element comprises a stent having barbs (98) to engage and retain the blocking element. The stent also has anchors (100) to retain the stent in a bronchial tube or tubule. A method of treatment of emphysema or other lung conditions or diseases in human or animal patients comprises placing an obturator in a bronchial tube or tubule of the patient so as to seal the tube or tubule against the passage of fluid past the obturator.

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OCCLUSION DEVICE

The present invention relates to a device useful in the treatment of emphysema and other diseases or disorders of the human or animal lung.

Emphysema is a disease of the lung caused primarily by prolonged smoking, although not exclusively thereby. It is an unrelentless, intractable and debilitating process. Emphysema is defined as an abnormal permanent enlargement of the air spaces distal to the terminal bronchioles, accompanied by destruction of their walls without obvious fibrosis. In this context, destruction means non-uniformity in the pattern of respiratory airspace enlargement; orderly appearance of the acinus is disturbed and may be lost.

Emphysema causes a physiological loss of lung elastic recoil, which decreases expiratory airflow by loss of driving pressure and premature airway closure from reduced airway traction. The effect of this is that the alveoli become hyper-inflated without there being any real exchange of air with the outside. Therefore the patient begins to feel starved of oxygen and so attempts

to breathe more deeply. In breathing more deeply, the effects are exacerbated.

Not only are those individual alveoli which have a block in their respective bronchial tubules affected, but also neighbouring alveoli, perhaps in other regions of the lung, which may otherwise be perfectly serviceable, become affected because the hyper-inflated alveoli pressurise neighbouring alveoli and prevent them from expanding fully. There is, of course, a relatively fixed "exchange" volume of an individual's lung, that is to say, the difference between the expanded volume and the deflated volume. Emphysema reduces the exchange volume because undeflated alveoli occupy that space. Consequently, the only recourse available to the patient is to increase the expanded volume, thereby resulting in the barrel chest symptomatic of emphysema sufferers.

The major therapeutic modalities currently available consist of bronchodilator and anti-inflammatory drugs, directed at decreasing airway resistance, and antibiotics to treat acute and chronic infection. Supplemental oxygen therapy for the hypoxaemic patient improves exercise performance and improves survival in patients with cor pulmonale. Despite all available medical therapies, the course of the disease is one of

progressive limitation, increasing dyspnoea and significant increase in overall mortality.

It has long been realised that full lung volume is more than enough for survival in most circumstances and that a person can survive quite satisfactorily with only one lung, for example. Heterogenous distribution of emphysema, together with the lack of pulmonary blood flow to those areas have made lung volume reduction surgery a logical option. Removal of parts of the lung affected by emphysema permits unaffected areas to become operative again and so enable a better quality of life for the patient. Clearly, however, such invasive procedures are of a very serious nature and some patients will not, in any event, be in a sufficiently strong condition to accept the trauma of such procedures. Primarily, the basic relief for emphysema sufferers is inactivity, on the one hand, and breathing pure oxygen, on the other.

Emphysema is a distressing condition affecting a relatively large proportion of the population, and a more effective and less traumatic treatment is required.

On a different matter, other lung conditions sometimes lead to bleeding into the lung. A patient having this condition feels movement of the blood caused by airflow in the lung during breathing, and perceives the blood as

a foreign body and irritant. The patient coughs in an attempt to dislodge the perceived foreign body. Coughing blood, of course, is sometimes the first warning of a more serious disease or condition, but once that is realised, there is no benefit in such bleeding. Moreover, in such conditions where the lung might heal itself and subsequently stop bleeding, or indeed simply where the bleeding needs to be confined, the coughing reaction, which is almost impossible to resist, does not help the situation at all, and merely spreads the blood to other areas of the lung.

Therefore it is an object of the present invention to provide a method of treatment of certain lung conditions or diseases and to provide a device for such treatment.

In accordance with a first aspect of the present invention there is provided a method of treatment of emphysema or other lung conditions or diseases, the method comprising placing an obturator in a bronchial tube or tubule so as to seal the tube or tubule against the passage of fluid past the obturator.

In the case of emphysema, and by the simple expedient of inserting an obturator in a bronchial tube, a section of a lung can be isolated so that no air can be drawn into it. Thereafter, the isolated part deflates in time as the

air remaining in it becomes absorbed, and so that part of the lung stops affecting other areas of the lungs, which can thus perform normally. Such a procedure is relatively simple, requiring only a delivery device for the obturator, which device is inserted through the mouth and airway of the patient until the proposed placement site is reached, whereupon the device is activated to release the obturator from the device.

In the case of bleeding into the lung, an obturator stops the flow of blood. The lung is tamponated by the obturator and blood merely collects in the isolated part of the lung and ultimately, if the bleeding stops, will be reabsorbed. Alternatively, in the case of some, perhaps terminal, conditions such as some lung cancers, it at least provides temporary relief for the patient.

In accordance with a second aspect of the invention there is provided an obturator for a bronchial tube or tubule of a human or animal lung comprising a blocking element and a securing element.

Preferably the two elements are separate components, the blocking element serving to seal the tube or tubule against the passage of fluid past the obturator when the obturator is disposed in a bronchial tube or tubule, and

the securing element serving to retain the blocking element in position in the tube or tubule.

The blocking element preferably comprises a substantially cylindrical plug of biocompatible material. The plug may comprise resiliently deformable closed-cell foamed plastics material, such as PVC, so that it may be compressed to facilitate insertion into the tube or tubule and thereafter expand to fill the cross-section of the tube or tubule.

It is known to employ stents in medical fields to expand and support collapsed blood vessels, and indeed bronchial tubes. A stent is a compressible framework which, when inserted into a vessel and released, expands and, within the limits of its expansion, supports and possibly expands the walls of the vessel.

Preferably, the securing element comprises a stent. The stent may have barbs to engage and retain the blocking element. The stent preferably also has anchors to retain the stent in a bronchial tube or tubule.

In one embodiment, the stent comprises a crown of surgical quality steel wire legs in zig-zag formation. Said barbs and anchors may depend from points of the

crown. Preferably the crown is closed in its circumference, although this is not essential.

In another embodiment, the stent comprises a dome of surgical quality steel wire legs. Said barbs and anchors may be formed on the ends of said legs.

It is known in medical fields to block blood vessels, for example where a genetic or other defect has resulted in a hole which needs blocking, or, for example, in the case of babies whose aortic to pulmonary artery connection has not closed following birth, a condition known as patent ductus arteriosus. In the case of holes, it is well known to employ an "umbrella", where a diaphragm of material forms the seal against the blood vessel wall, the handle of the umbrella serving to keep the diaphragm across the vessel. In the case of babies, it has also been known to employ a plug of PVC foam to treat patent ductus arteriosus, the plug encouraging clotting.

However, in the case of bronchial tubes and tubules a diaphragm seal is not been used yet, although its application cannot be entirely ruled out. For example, an umbrella device with a larger surface area of contact with the bronchial mucosa might be as effective.

In blood vessels a complete seal is seldom required because any leak soon blocks by the formation of a clot; something that would not happen in an airway of a lung. Secondly, airways are not always absolutely circular in section, so a circular diaphragm may not always make a good seal, at least around some parts of the circumference, unless it has capacity to expand in all radial directions and has a large contact area.

However, a complete seal is an absolute requirement of the present invention (at least over the period of a single breath), because without it, air can leak past during inhalation and pressurise the lung in just the same way, and perhaps even to a greater extent. More importantly, however, a patient with such an obturator in place can only feel its presence if there is movement of air around it to stimulate adjacent nerve endings. Once a patient can feel the obturator, there will be irresistible compulsion to cough which, if done excessively, may be sufficient to dislodge the obturator.

Thus it has been found that a very effective seal is achieved by the use of said cylindrical plug of foamed PVC (of the type commonly employed as earplugs). The effectiveness of this arrangement is probably due to the fact that any leakage path has to be a long one and there are thus numerous opportunities for it to close and seal

about at least one closed circuit around the plug. Another reason is that a plug can mould itself to the shape of the tube or tubule, which is itself unlikely to be cylindrical, or, indeed, circular in cross-section.

Preferably, the method of the present invention employs an obturator of the type defined above.

The delivery device preferably comprises a delivery tube in which the obturator is received in a compressed state at a distal end thereof, a guide tube, which is capable of following a possibly tortuous path under the guidance of a surgeon from entry into the mouth of a patient, down the patient's trachea and one bronchus to a proposed delivery site in a bronchial tube or tubule, and which has a passage to receive the delivery tube therealong, and release means to eject the obturator from the delivery tube and guide tube.

The obturator needs to slide in the delivery tube during ejection and the stent provides a low friction surface of the obturator to facilitate such ejection.

It is feasible that the blocking and securing elements may be integrally formed from plastics material, and wherein the securing element comprises adhered or fused anchor elements on the blocking element.

It is also feasible that the securing element may comprise a memory metal which is released to its normal expanded shape by a physical parameter, for example, the passage of an electric current therethrough, once it has been inserted at the proposed location. Otherwise it is in the same form as the above described steel stent which relies on resilience for its expansion. The advantage of a memory metal device is that it requires no compression during insertion so that the delivery tube of the delivery device may be replaced by a simple guide rod to which it is connected.

The invention will be better understood from the following description of particular embodiments given as non-limiting examples. The description refers to the accompanying drawings, in which :-

Figure 1 shows a section through the human chest indicating the location of bronchial obturators in the lungs;

Figure 2 shows a bronchial obturator complete with delivery system;

Figures 3a b and c show in perspective two embodiments of an obturator according to the present invention, that of Figure 3a having a crown stent, and that of Figure 3b having a dome stent, Figure 3c being a

crown stent in an open configuration prior to rolling and, optionally, welding into a ring as in Figure 3a;

Figures 4a and b show an internal barb and external anchor respectively;

Figure 5 is a perspective view of another embodiment of obturator in accordance with the present invention; and,

Figure 6 is a perspective view of yet another embodiment of obturator also in accordance with the present invention.

In Figure 1 of the drawings, a human chest cavity 10 includes a pair of lungs 12 which each comprise upper and lower lobes 14,16. A trachea 18 branches into two bronchi 20, which further branch into bronchial tubes 22 and segmental bronchi 24. The bronchi 24, after further branching, terminate in alveoli 26.

In the majority of patients suffering from emphysema, it frequently effects mainly the upper lobes 14 of the lungs, leaving the lower lobes 16 unaffected, or at least less affected. However, if no treatment is given to a patient, the expansion effect of the upper lobes as the condition develops presses on the lower lobes and reduces their capacity to perform efficiently. Lower lobe emphysema does occur in some patients, and in which event it is then the upper lobes which are compressed.

Thus the present invention suggests placing an obturator 50 in a bronchial tube or tubule to isolate the region of the lung supplied by that tube or tubule. Where the obturator is placed will be decided by the surgeon and will depend on the how localised the damaged region of lung is. That is to say, if the whole lobe is badly affected, then the obturator is placed in the lobar bronchus 22 supplying that lobe (as shown at 50 in Figure 1). On the other hand, if the damage is more localised, then the obturator will be placed in a smaller segmental bronchus 24, (as shown at 50' in Figure 1). Thus more than one obturator may be employed in the same pair of lungs isolating different regions of them. They will also be of different sizes, depending where they are to be inserted.

The above considerations equally apply when the condition being treated is not emphysema but some other condition which a doctor considers can usefully be treated by the method of the present invention. Such another condition is where a lung, or part of it is bleeding into the airway and an obturator isolates the bleeding region and inhibits coughing which may damage the lung further, or at least cause further discomfort to the patient.

Figure 2 shows an endo-bronchial obturator 50 complete with delivery device 70. The delivery device comprises a

handle 72 and flexible guide tube 74. Slidably received in the guide tube is a delivery tube 76 having the obturator 50 disposed at its distal end 78. A release means 80 is insertable in a proximal end 82 of the delivery tube 82 and by means of which the obturator 50 may be ejected from the end of the delivery tube. The guide tube is guided down the trachea and into the appropriate bronchus by means of guide lines (not shown) which enable the delivery system to be turned to follow the desired course. Optical guidance means may be included, or real-time X-ray or other monitoring methods may be employed to guide the surgeon. Once the end of the guide tube reaches the correct location, the delivery tube is inserted in the handle end of the delivery device 70, and then the release means 80 is pushed down the tube 82 to eject the obturator. The obturator is adapted to expand or be expanded, when ejected, to fill and block the tube or tubule in which it is inserted.

As can be seen from Figure 3a, the obturator 50 in its first embodiment is comprised of two main components, a securing element in the form of a stent 90, and a blocking element in the form of a closed-cell, PVC foam plug 92.

The stent 90 is constructed from a plurality of legs 91 of surgical grade stainless steel wire welded together

such that when extended the stent appears as a series of connected 'W's, as shown in an unconnected disposition in Figure 3c. Indeed, it is not essential that the final connection between ends 94,96 be made to form a closed crown arrangement (as shown in Figure 3a); it is equally effective merely to roll the stent 90b as indicated by arrows in Figure 3c.

When the two ends of the stent are joined together, the stent 90 folds into a circular frame or crown, capable of encompassing the biocompatible block 92. The stent is constructed so as to be of a size slightly smaller (in its unstressed condition) than the block, so that its natural resilience squeezes the block slightly. On the other hand, the stent should be larger than the airway into which it is to be introduced so that it presses outwardly against the wall of the airway, and is incorporated into the mucosa of the air passage.

The legs 91 of the stent crown are fitted with both internal barbs 98 and external anchors 100. The barbs 98 embed themselves in the block 92 and secure the block to the stent 90. The anchors 100 are adapted to engage the walls of the patient's airways to hold the stent in position.

Figure 4a shows an internal barb 98. The internal barb, also constructed from surgical quality stainless steel, is substantially straight and has a hook 99 at one end. The hooked end 99 is the point and means by which the barb is secured to the biocompatible block.

Figure 4b shows an external anchor 100. The anchor, which is also constructed from surgical quality stainless steel, is again substantially straight and has a coil 101 at its end. A coil is used so that damage is not caused to the tissue of the airway in which the obturator is fitted, particularly if and when the obturator is removed.

The barbs and anchors are joined to the stent crown by a welded joint between two adjacent legs 91. Barbs can alternate with anchors at the same end of the stent, or one end can have all barbs, while the other end has all anchors. Both arrangements are shown in Figures 3a and c respectively.

A different embodiment of obturator 50b, also in accordance with the present invention, is shown in Figure 3b in which surgical quality stainless steel wires are all welded together at a point 104 to form a domed stent 90b. Legs 91b are alternately turned inwards to form barbs 98b, or outwards to form anchors 100b.

Alternatively, all the legs could be anchors 100b, with interspersed shorter barbs 98bb, as one is shown in dashed lines in Figure 3b.

The aforementioned obturators all rely on resilience of the steel to return the stent to its original shape once released from the delivery mechanism and so as to enable fitment in a narrower tubule than the unstressed size of the stent would otherwise allow. However, this requires prestressing the stent and keeping it stressed during delivery. Thus the present invention may find suitable application for memory metals, which only return to their original shape when some physical condition changes, for example, temperature rise or electrical current flow.

It is essential for the blocking device 50 to be comprised of a resiliently deformable material such as PVC foam as mentioned above. This enables the blocking device to be easily surrounded by the stent 90 and deformed into a compact structure, thereby enabling delivery of the block to its destination in the lung.

It is likewise essential that the block be capable of expanding and reforming into its original shape once deposited in the desired location in the lungs. It should be noted that the block is deformed and reformed in both an axial and a radial direction. It is the block 92

which seals a bronchial tube or tubule; mucous surrounds the block and forms a fluid tight seal. The presence of the stent around the block does not inhibit sealing in any way since the stent is essentially incorporated into the mucosa lining the airway.

Under compression, PVC foam has a high coefficient of friction which would prevent ejection from the delivery device as described above, if it was not surrounded by the stent 90, which offers a relatively low friction surface to the inside of delivery tube 76.

However, it is feasible that the block 92 could include a low friction surface to enable such ejection without the stent. Instead of the stent as described above, anchor means might be moulded in biocompatible plastics material as a crown, for example, on one end of the block, and either be adhered, fused or otherwise bound thereto.

The effectiveness of the device depends, to some extent, on the length of the block. Moreover, the block is required to be of a size which is both comfortable to the patient once expanded in the lung and which expands to completely obstruct the passage of air into the affected portions of the lung. The extended size of the block therefore ranges between 5mm and 25mm in length, and

between 5 and 11mm in diameter, depending on the size of the tube or tubule to be obturated.

Obturator 50c shown in Figure 5, comprises a balloon 200, which is inflated after insertion and then detached. The balloon is captivated in an appropriate securing device such as stent 202. In this case, the barbs would not be sharp, but would merely retain ends of the balloon, or, as shown, would comprises turned-in points 204,206 at each end of the stent.

Finally, as mentioned above, the obturator may be as shown at 50d in Figure 6, where it comprises a diaphragm 300 expanded by an internal stent 302 having anchors 302. One end 306 of the diaphragm is attached to the stent to retain it on the stent. The diaphragm is also adhered to the stent.

While the obturator and method of the present invention has been described with reference to human patients, animal patients may in certain circumstances also benefit.

The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and which are open to public inspection with this

specification, and the contents of all such papers and documents are incorporated herein by reference.

All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

Each feature disclosed in this specification (including any accompanying claims, abstract and drawings), may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each feature disclosed is one example only of a generic series of equivalent or similar features.

The invention is not restricted to the details of the foregoing embodiments. The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

CLAIMS

1. An obturator for a bronchial tube or tubule of a human or animal lung comprising a blocking element and a securing element.

2. An obturator as claimed in claim 1, in which the two elements are separate components, the blocking element serving to seal the tube or tubule against the passage of fluid past the obturator when the obturator is disposed in a bronchial tube or tubule, and the securing element serving to retain the blocking element in position in the tube or tubule.

3. An obturator as claimed in claim 1 or 2, in which the blocking element comprises a substantially cylindrical plug of biocompatible material.

4. An obturator as claimed in claim 3, in which the plug comprises resiliently deformable closed-cell foamed plastics material, such as PVC.

5. An obturator as claimed in any preceding claim, in which the securing element comprises a stent.

6. An obturator as claimed in claim 5, in which the stent has barbs to engage and retain the blocking element.

7. An obturator as claimed in claim 5 or 6, in which the stent has anchors to retain the stent in a bronchial tube or tubule.

8. An obturator as claimed in claim 5, 6 or 7, in which the stent comprises a crown of surgical quality steel wire legs in zig-zag formation.

9. An obturator as claimed in claims 6, 7 and 8, in which said barbs and anchors depend from points of the crown.

10. An obturator as claimed in claim 8 or 9, in which the crown is closed in its circumference.

11. An obturator as claimed in claim 5, 6 or 7, in which the stent comprises a dome of surgical quality steel wire legs.

12. An obturator as claimed in claim 11, when dependent on claim 6, in which said barbs are formed on the ends of said legs.

13. An obturator as claimed in claim 11 or 12, when dependent on claim 7, in which said anchors are formed on the end of said legs.

14. An obturator as claimed in any preceding claim, further comprising a delivery device, which device comprises a delivery tube in which the obturator is received in a compressed state at a distal end thereof, a guide tube, which is capable of following a path under the guidance of a surgeon to a proposed delivery site in a bronchial tube or tubule, and which has a passage to receive the delivery tube therealong, and release means to eject the obturator from the delivery tube and guide tube.

15. An obturator as claimed in claim 14, when dependent on claim 5, in which the stent provides a low friction surface of the obturator to facilitate such ejection.

16. An obturator as claimed in claim 1, in which the blocking and securing elements are integrally formed from plastics material, and wherein the securing element comprises adhered or fused anchor elements on the blocking element.

17. An obturator as claimed in claim 2, in which the securing element comprises a memory metal which is

released to its normal expanded shape by a physical parameter when it has been inserted at the proposed location.

18. An obturator as claimed in claim 17, in which said physical parameter is the passage of electrical current through the securing means.

19. An obturator as claimed in claim 1 or 2, in which the blocking element comprises a balloon.

20. An obturator as claimed in claim 19, in which the securing element comprises a stent, points of the stent being turned inwardly to captivate the balloon.

21. An obturator as claimed in claim 1 or 2, in which the blocking element comprises a diaphragm.

22. An obturator as claimed in claim 21, in which the securing element comprises a domed stent secured at its point to the centre of the diaphragm, the legs of the stent pressing the diaphragm against the mucosa of a bronchial tube when inserted therein.

23. A method of treatment of emphysema or other lung conditions or diseases in human or animal patients, the method comprising placing an obturator in a bronchial

tube or tubule of the patient so as to seal the tube or tubule against the passage of fluid past the obturator.

24. A method as claimed in claim 23, in which the obturator is put in place in a patient by use of a delivery device for the obturator, which device is inserted through the mouth and airway of the patient until the proposed placement site is reached, whereupon the device is activated to release the obturator from the device.

25. A method as claimed in claim 23 or 24, which method employs an obturator of the type claimed in any of claims 1 to 22.

26. An obturator substantially as hereinbefore described with reference to any of the accompanying drawings.

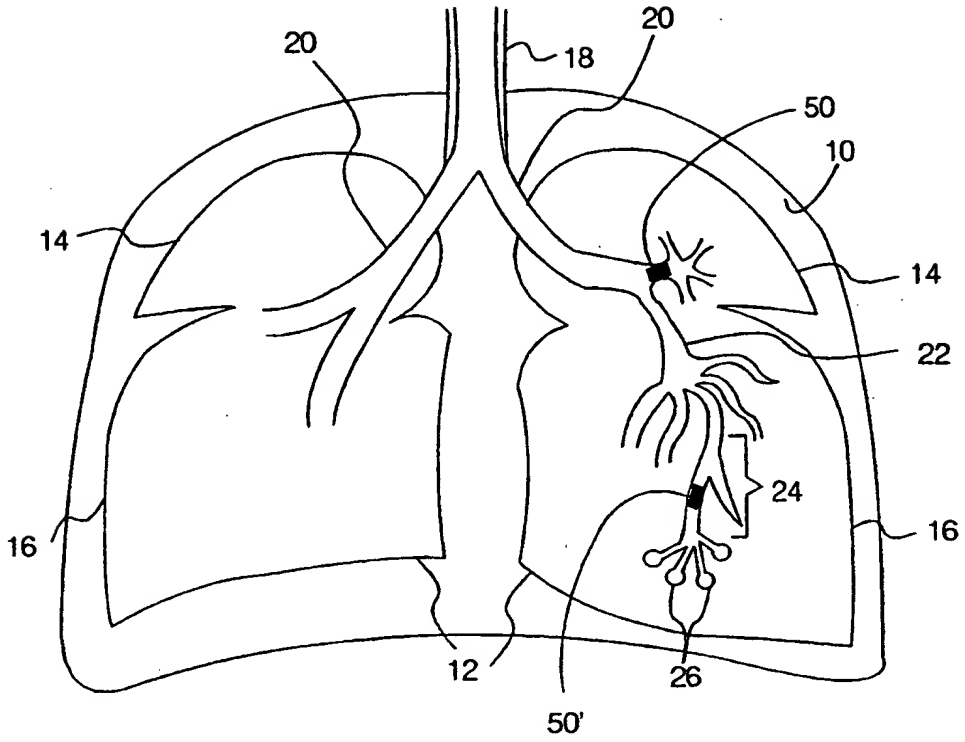

Fig. 1

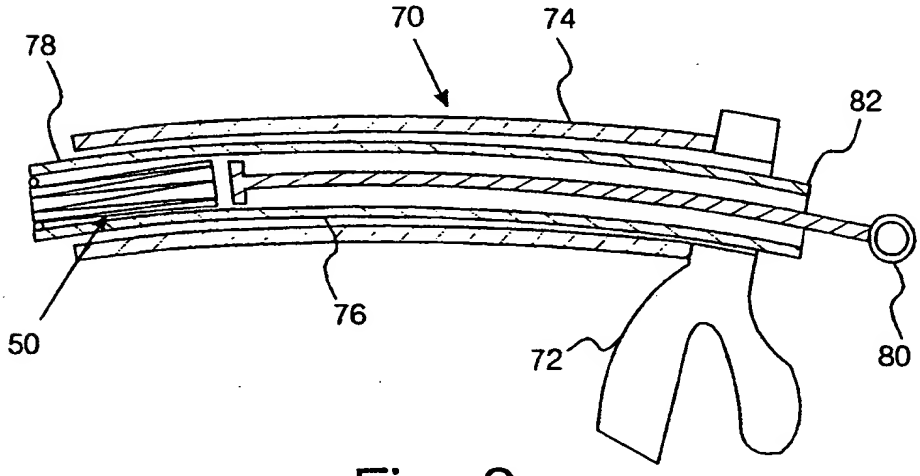

Fig. 2

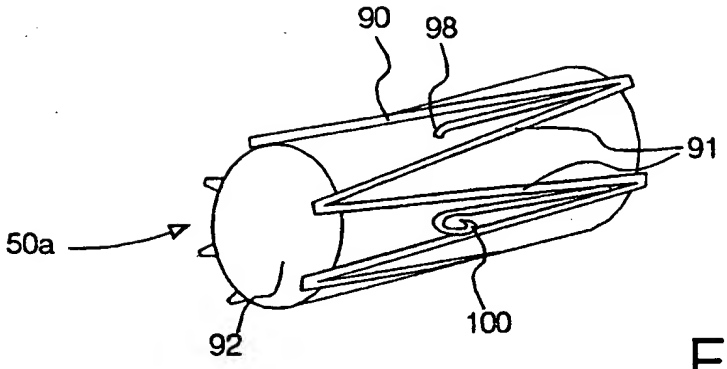

Fig. 3a

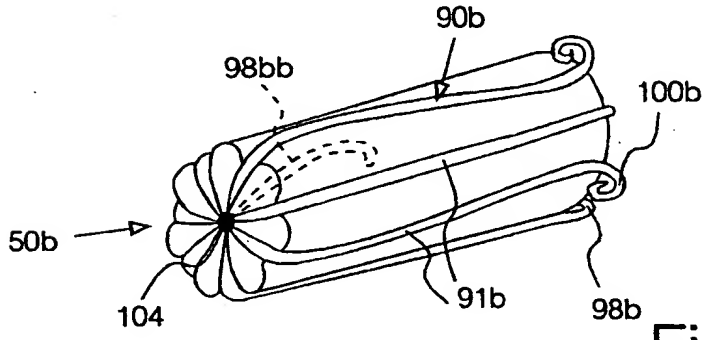

Fig. 3b

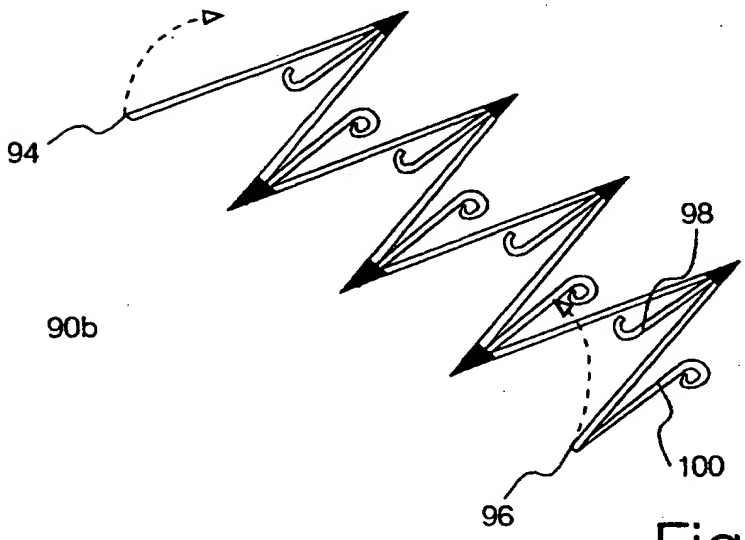

Fig. 3c

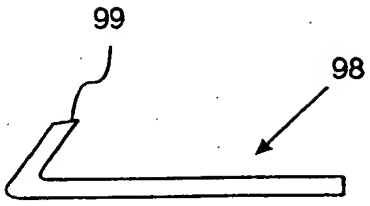

Fig. 4a

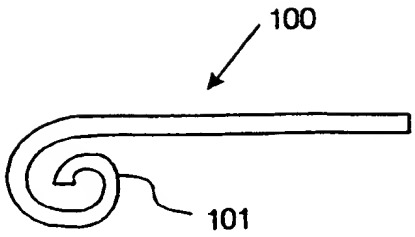

Fig. 4b

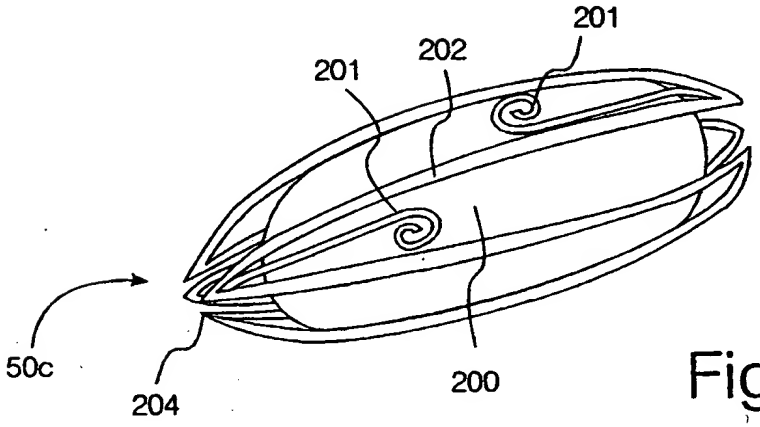

Fig. 5

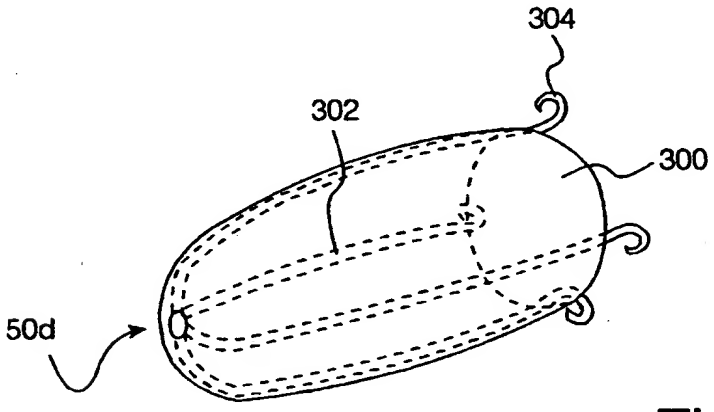

Fig. 6

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/GB 98/00652

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 382 261 A (PALMAZ) 17 January 1995 see the whole document ---	1-3,5, 10,14, 15,21
X	DE 92 05 797 U (SCHMITZ-RODE ET AL.) 17 June 1992 see the whole document ---	1-3,5-7, 11-13, 17,21,22
X	WO 95 32018 A (TEIRSTEIN) 30 November 1995 see abstract; figures ---	1-3,19, 21
X	US 4 710 192 A (LIOTTA ET AL.) 1 December 1987 see abstract; figures see column 5, line 23-40 ---	1,2,5,7, 21
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 June 1998	24/06/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Giménez Burgos, R

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/GB 98/00652

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 204 218 A (STÖCKERT INSTRUMENTE GMBH) 10 December 1986 see column 2, line 14-49; figures	1-3,16, 19
A	WO 94 26175 A (VITAPHORE CORPORATION) 24 November 1994 see abstract; figures	4,14
A	US 5 246 445 A (YACHIA ET AL.) 21 September 1993 see abstract; figures see column 2, line 65-68	1
A	DE 41 01 936 A (FISCHER ET AL.) 23 July 1992 see the whole document	1

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 98/ 00652

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte onal Application No
PCT/GB 98/00652

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5382261 A	17-01-1995	US 5656036 A	12-08-1997
DE 9205797 U	17-06-1992	NONE	
WO 9532018 A	30-11-1995	US 5499995 A	19-03-1996
		AU 2605495 A	18-12-1995
		CA 2191091 A	30-11-1995
		EP 0788391 A	13-08-1997
		JP 10500873 T	27-01-1998
US 4710192 A	01-12-1987	NONE	
EP 0204218 A	10-12-1986	DE 3519626 A	04-12-1986
		JP 1621967 C	09-10-1991
		JP 2047230 B	18-10-1990
		JP 61279256 A	10-12-1986
WO 9426175 A	24-11-1994	NONE	
US 5246445 A	21-09-1993	IL 94138 A	18-03-1997
		AU 651826 B	04-08-1994
		AU 7799491 A	11-11-1991
		CA 2080905 A	20-10-1991
		DE 69126428 D	10-07-1997
		DE 69126428 T	30-10-1997
		EP 0525110 A	03-02-1993
		EP 0723765 A	31-07-1996
		WO 9116005 A	31-10-1991
DE 4101936 A	23-07-1992	NONE	

Online European Patent Register - Results

Status of the database as of 05-09-2001 (dd-mm-yyyy)

Choose your View: All data mentioned in Rule 92 and EPIDOS

Return to Search Screen

Publication numbers, publication type and publication dates	
	WO9848706 05-11-1998 [1999/14]
Application numbers and filing date	
	EP19980908220 (98908220.1)
Date of filing	03-03-1998
	WO1998GB00652
Date of publication of search report	
Date of international search report	05-11-1998
International Searching Authority	EP
Priority number, priority date	
	GB19970008681 30-04-1997
Classification (IPC)	
	A61B17/12
Designated states	
	AT , BE , CH , DE , DK , ES , FR , GB , GR , IE , IT , LI , LU , MC , NL , PT , SE , FI
English title	
	OCCLUSION DEVICE
French title	
	DISPOSITIF OCCLUSIF
German title	
	VERSCHLUSSVORRICHTUNG
Designated states, applicant name, address	
	FOR ALL DESIGNATED STATES Bradford Hospitals NHS Trust Duckworth Lane Bradford, West Yorkshire BD9 6RY/GB
Inventor name, address	
	01 / SABANATHAN, Sabaratnam +di / / /
Representative name, address	
	Lunt, Mark George Francis, et al Harrison Goddard Foote, Fountain Precinct, Leopold Street Sheffield S1 2QD/GB
Filing language	
	EN
Procedure language	
	EN
Location of file and fax number for file inspection requests	
Application is treated in (/fax-nr)	THE HAGUE/(+31-70) 3403016
PCT: Acts performed for entry into EPO regional phase	
Acts performed for entry into the regional phase	25-02-2000
- National basic fee paid	25-02-2000
- Designation fee(s) paid	25-02-2000
Examination procedure	
Date of request for preliminary examination	19-11-1998
Request for decision	(all rights)
date request/result + date	13-09-2000/(open) 00000000
Application withdrawn or deemed to be withdrawn	
Communication, that the application is deemed to be withdrawn	
date dispatch/legal effect date	27-07-2000/00000000
Reason	A.90(3)/A.78(2)/R.15(2)/R.25
Renewal fees	
Renewal fee A.86 (patent year / paid)	03/25-09-2000

04/15-05-2001

Penalty Fees

Communication R85A designation fee
country/dispatched/time-limit/payment

AT/12-01-2000/M01/25-02-2000
BE/12-01-2000/M01/25-02-2000
CH/12-01-2000/M01/25-02-2000
DE/12-01-2000/M01/25-02-2000
DK/12-01-2000/M01/25-02-2000
ES/12-01-2000/M01/25-02-2000
FI/12-01-2000/M01/25-02-2000
FR/12-01-2000/M01/25-02-2000
GB/12-01-2000/M01/25-02-2000
GR/12-01-2000/M01/25-02-2000
IE/12-01-2000/M01/25-02-2000
IT/12-01-2000/M01/25-02-2000
LU/12-01-2000/M01/25-02-2000
MC/12-01-2000/M01/25-02-2000
NL/12-01-2000/M01/25-02-2000
PT/12-01-2000/M01/25-02-2000
SE/12-01-2000/M01/25-02-2000

Communication R85B examination request
date dispatch/time-limit/payment date

12-01-2000/M01/00000000

Communication R85A national basic fee
date dispatch/time-limit/payment date

12-01-2000/M01/25-02-2000

Additional fee A.86(2)
year/due date/time-limit/payment date

03/31-03-2000/M06/25-09-2000
04/31-03-2001/M06/15-05-2001

Documents cited in the International Search

US5382261 A [X];
DE9205797U U [X];
WO9532018 A [X];

US4710192 A [X];
EP0204218 A [X];
WO9426175 A [A];

US5246445 A [A];
DE4101936 A [A]

Documents cited by the Applicant

None

[End of Data]

Return to Search Screen
06-09-2001 08:32:29

Enquiries on this matter should be made to: David Jackson

Tel: 01274 364788 Our ref: DJ.DS.jr271097
Fax: 01274 364786 Your ref:

Bradford Hospitals NHS Trust

Bradford Royal Infirmary
Duckworth Lane
Bradford
BD9 6RJ

Tel: (01274) 542200

27 October 1997

Mr J Richardson
Consultant Anaesthetist
Department of Anaesthetics
BRI

Dear Dr Richardson

PATENT APPLICATION FOR LUNG OBDURATOR

Following your recent discussions on behalf of the Sabanathan family in respect of the above, I understand from Bob Dugdale that an agreement has been reached in respect of any profits which may accrue from the commercial development of the device.

The Trust, as holder of the Patent Application, would expect to progress and fund the patent to the second stage of the registration process in April 1998, when foreign patents would be pursued through a PCT application.

This would extend the patent protection for a further 18 months, during which time it would be expected that any commercial interest in the product would be registered.

If any such commercial interest is manifested as income to the Trust, the organisation would expect, as a first call against this, to recoup the expenditure incurred in pursuing the patent.

In terms of any income generated over and above this, and in view of the very significant contribution that Mr Sabanathan made to the development of Surgery in Bradford, the Trust would divide this profit on the basis of a 50:50 split with the Sabanathan estate.

It is deeply regrettable that these discussions have been necessitated by the sad and untimely death of Mr Sabanathan but I hope that the situation is now resolved to the satisfaction of all concerned.

With best wishes.

Yours sincerely

David Jackson

DAVID JACKSON
Chief Executive

PRIVATE & CONFIDENTIAL
Mr. D. Jackson, Chief Executive
Bradford Hospitals NHS Trust
Duckworth Lane
BRADFORD BD9 6RJ

Our Ref: SEC.TMH.
Your Ref:

31 March 1998

Dear Mr. Jackson

Mr. Sabanathan - Lung Obdurator

The Sabanathan family have passed to me your letter of 27th October 1997 addressed to Mr. J. Richardson together with various correspondence relating to the patent application.

Whilst I believe that an understanding has been reached in respect of profits which may accrue from the commercial development of the device, I have expressed a view to the Sabanathan family that the letter of the 27th October is not set out clearly enough to protect them.

As it may be quite some time before any commercial development of the device produces financial benefit, the parties may by that time be unclear as to what has been agreed and indeed, the faces may have changed.

As I understand it, any financial benefit obtained through the commercial development of the device, the exploitation of a patent or any other commercial interest in the product would, after the deduction of certain expenditure, be split 50:50 between the Trust and the Sabanathan estate.

The agreement relates to financial benefit received as capital, income, or in any other form whatsoever (for example, from an outright sale or assignment of rights under the patents).

The expenditure the Trust can first recoup, we understand, is the actual legal costs and expenses in prosecuting the patent applications.

continued.....

11-19 Westgate, Shipley, West Yorkshire, BD18 3QX
Tel: 01274 585459 Fax: 01274 531334 DX: 20901 Shipley
e-mail: srbstell@lcfeather.yorks.com

Continued...

31 March 1998

I shall be grateful if you could confirm that the above sets out your understanding of the agreement reached. It will obviously be subject to this agreement that Mrs. Sabanathan's cooperation on behalf of her late husband in respect of any application, will be forthcoming.

Equally, you will appreciate that Mr. Sabanathan was passionate in the pursuit and development of the lung obdurator. For this reason, the Sabanathan family would look to its success as being a fitting tribute to such passion and enthusiasm. Mrs. Sabanathan is disappointed that no further consultation has taken place with her in relation to the British patent, but I hope you will be able to confirm to me that her husband is indeed named as inventor of the device and is gratified to note from Dr. Dugdale's letter to Mr. Lunt at Dibb Lupton Alsop, which has been copied to her, that it would appear that Mr. Sabanathan is in respect of the PCT application, being named as inventor.

Mrs. Sabanathan would however wish to see the title of the invention, both on the PCT and on the British patent, bearing her husband's name, such as "Saba's Lung Treatment Device".

Accordingly, I look forward to hearing from you.

Yours sincerely

SUSAN E. CLARK

Last Cawthra FEATHER

SOLICITORS

Dr. Dugdale
Bradford Royal Infirmary
Bradford

BY FAX: 01274 364134

Our Ref: SEC.TMH.40484
Your Ref:

31 March 1998

Dear Dr. Dugdale

Mr. Sabanathan - Lung Obdurator

I attach a copy of the letter that I am today sending to Mr. Jackson's office. This I believe does in actual fact set out and reflect the agreement that has been reached.

I have asked Mrs. Sabanathan to execute the Power of Attorney required for the PCT application and to let you have that back as quickly as possible.

The release to you of the Power of Attorney is obviously on the assumption that the agreement between the parties is as set out in the attached letter, that you keep us updated on a regular basis of the progress of the patents and any further development of the invention and that even though the title of the inventions on the patent application may not be in Mr. Sabanathan's name, the device itself will as far as it is within the Trust's power to procure, be known as "Sabanathan's Lung Obdurator".

If you have any queries, please give me a call.

Yours sincerely

SUSAN E. CLARK

11-19 Westgate, Shipley, West Yorkshire, BD18 3QX
Tel: 01274 585459 Fax: 01274 531334 DX: 20901 Shipley
e-mail: srbstell@lcfeather.yorks.com

POWER OF ATTORNEY

(for an international application filed under the Patent Cooperation Treaty)

(PCT Rule 90.4)

The undersigned applicant(s) *(Names should be indicated as they appear in the request)*:

SABANATHAN, THIRUMANI
8 FOSTER PARK ROAD
DENHOLME
BRADFORD
WEST YORKSHIRE BD13 4BE
UNITED KINGDOM

hereby appoints (appoint) the following person as: [X] agent [ ] common representative

Name and address
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

LUNT, MARK GEORGE FRANCIS
DIBB LUPTON ALSOP
FOUNTAIN PRECINCT
BALM GREEN
SHEFFIELD S1 1RZ
UNITED KINGDOM

to represent the undersigned before

[X] all the competent International Authorities

[ ] the International Searching Authority only

[ ] the International Preliminary Examining Authority only

in connection with the international application identified below:

Title of the invention: LUNG TREATMENT DEVICE

Applicant's or agent's file reference: P70357WO

International application number (if already available):

filed with the following Office _____ as receiving Office
and to make or receive payments on behalf of the undersigned.

Signature of the applicant(s) *(where there are several applicants, each of them must sign; next to each signature, indicate the name of the person signing and the capacity in which the person signs, if such capacity is not obvious from reading the request or this power)*:

S Palanathan.

Date: 31 - 3 - 98.

AGREEMENT

This Agreement (this "Agreement") is made and entered into effective as of June 6, 2000 ("the Effective Date") by and between

The Foundry, LLC, a Delaware limited liability corporation ("Foundry"),

Bradford Hospitals NHS Trust, a Trust organized and subsisting under the laws of the United Kingdom, of Duckworth Lane, Bradford, West Yorkshire, BD9 6RY, GB ("NHS Bradford"), and

Thirumani Sabanathan, a United Kingdom citizen of 2A The Knoll, Calverley, Leeds, LS28 5FB, GB ("Sabanathan").

RECITALS

NHS Bradford and Sabanathan are between them the owner of the Technology (as defined below), and NHS Bradford and Sabanathan desire to assign and transfer to Foundry all of their respective right, title and interest in and to the Technology, and other related rights.

NOW THEREFORE, the parties hereby agree as follows:

1. Definition of Assigned Assets. As used herein, "Assigned Assets" means:

(a) The Technology, which is defined as information, trade secrets, know-how, intellectual property rights, clinical information, prototypes, or test data related to devices, systems, methods, or procedures for bronchial occlusion for isolation of diseased sections of lungs. Any information, prototypes, or other work in the field of this procedure performed directly by the late Dr. Sabanathan or by any associates, consultants, or related companies also constitutes the Technology.

(b) All worldwide patents, patent applications, patent rights, copyrights, copyright registrations, moral rights, trade secrets, know-how, mask work rights, rights in trade dress and packaging, and goodwill directly relating to the Technology, whether arising under the laws of the United Kingdom, the United States of America or the laws of any other state, country or jurisdiction existing at the date of this Agreement. This includes the pending United Kingdom patent application number 9708681.3 and the international application number PCT/GB98/00652 ("the Applications") and any additional, continuation, continuation-in-part, or division thereof or any substitute application therefore, any reissue, extension, or patent term extension of any such patent, and any foreign counterpart of the foregoing.

(c) All documentation, drafts, papers, designs, schematics, diagrams, models, prototypes, source and object code (in any form or format and for all hardware platforms), computer-stored data, diskettes, manuscripts and other items describing all or any part of the Technology or any information related thereto or in which all or any part of the Technology, any intellectual property right or such information is set forth, embodied, recorded or stored existing at the date of this Agreement ("Information") but specifically excluding any Information that is in the possession of Sabanathan which it is hereby agreed by both the Foundry and by NHS Bradford that Sabanathan shall be entitled to retain.

2. Assignment.

(a) Subject to paragraph 2(b) NHS Bradford and Sabanathan shall sell, assign, transfer, release, quitclaim and convey to Foundry, NHS Bradford's and Sabanathan's entire right, title and interest in and to each and all of the Assigned Assets. Save that it is specifically agreed by Foundry that Sabanathan shall be entitled to publish or commission the publishing of Dr. Sabanathan's work notwithstanding that it does or may include the use of intellectual property rights contained in the Assigned Assets and she shall be entitled to keep copies of any documentation drafts papers or disks in her possession to enable her to do so. Without limiting the foregoing, NHS Bradford and Sabanathan agrees to assign all their respective right, title and interest in and to the Applications; and all their respective right to file or prosecute patent applications covering the Assigned Assets in any jurisdiction in the world. Foundry acknowledges that it is aware that the period within which national/regional phase entry of international application no PCT/GB98/00652 must normally be effected may have passed without such phases having been entered and therefore such application may not exist as an asset unless the Entitlement Proceedings (as defined below) are successful and the application is thereafter permitted to proceed in the name of Sabanathan.

(b) If Foundry is in breach of its obligations under paragraphs 6 or 7 of this Agreement and in the case of paragraph 6 has not cured such breach within thirty (30) days of written notification thereof by NHS Bradford and/or Sabanathan and in the case of paragraph 7 has not taken reasonable steps to cure such breach within such 30 day period, it shall upon receipt of notice in writing from NHS Bradford and/or Sabanathan transfer and convey back to NHS Bradford and Sabanathan jointly in equal shares all its right title and interest in the Assigned Assets.

3. Reports. NHS Bradford agrees that it will, within thirty (30) days of the Effective Date hereof, arrange for the preparation and delivery to Foundry (and copied to Sabanathan) of one or more written reports describing in reasonable detail the efforts undertaken and the results obtained, with respect to any patenting, prototyping, testing and other development work performed by or on behalf of NHS Bradford with respect to the Assigned Assets. These Report(s) shall be treated as confidential information, to protect the patentability of any information contained therein.

4. NHS Bradford Warranties.

(a) NHS Bradford represents and warrants to Foundry to the best of its knowledge and belief that Dr. Sabanathan was the only inventor and/or author of, and that NHS Bradford and Sabanathan between them own, and can grant exclusive worldwide right, title and interest in and to, each of the Assigned Assets and that none of the Assigned Assets are subject to any dispute, claim, prior license or other agreement, assignment, lien or rights of any third party, or any other rights that might interfere with Foundry's use, or exercise of ownership of, any Assigned Assets (save as aforesaid in relation to the said international application). NHS Bradford further represents and warrants to Foundry to the best of its knowledge and belief that the Assigned Assets are free of any claim by any third party of any kind in or to any of the Assigned Assets.

(b) Sabanathan represents and warrants to Foundry to the best of her knowledge and belief that Dr. Sabanathan was the only inventor and/or author of, and that NHS Bradford and Sabanathan between them own, and can grant exclusive worldwide right, title and interest in and to, each of the Assigned Assets and that none of the Assigned Assets are subject to any dispute, claim, prior license or other agreement, assignment, lien or rights of any third party, or any other rights that might interfere with Foundry's use, or exercise of ownership of, any Assigned Assets (save as aforesaid in relation to the said international application). Sabanathan further represents and warrants to Foundry to the best of her knowledge and belief that the Assigned Assets are free of any claim by any third party of any kind in or to any of the Assigned Assets.

(c) NHS Bradford certifies that NHS Bradford has no outstanding agreement or obligation that is in conflict with any of the provisions of this Agreement, or that would preclude NHS Bradford from complying with the provisions hereof, and further certifies that NHS Bradford will not enter into any such conflicting Agreement in the area of the Assigned Assets during the term of this Agreement.

(d) Sabanathan certifies that Sabanathan has no outstanding agreement or obligation that is in conflict with any of the provisions of this Agreement, or that would preclude Sabanathan from complying with the provisions hereof, and further certifies that Sabanathan will not enter into any such conflicting Agreement in the area of the Assigned Assets during the term of this Agreement.

(e) NHS Bradford and Sabanathan agree to promptly commence proceedings ("Entitlement Proceedings") in the United Kingdom Patent Office to have the matter of their respective entitlements to the Applications determined by the comptroller of the Patent Office. NHS Bradford and Sabanathan have entered an agreement to that effect dated _____ and, in the event that Sabanathan is determined to be entitled to the rights in the Applications, and in consideration of NHS Bradford not disputing the Entitlement Proceedings, Sabanathan has agreed to assign an equal share in the rights in the Applications to NHS Bradford.

(f) NHS Bradford and Sabanathan covenant that they shall perfect the assignment ("Perfection") agreed by them in this Agreement as soon as practicable within thirty days of final conclusion of the Entitlement Proceedings by executing an Assignment as set out in Schedule I hereto or in such other form as are agreed between the parties hereto.

5. Further Assurances.

(a) NHS Bradford and Sabanathan further agree that, after such Perfection, they will execute one or more patent assignments covering the Assigned Assets, to be filed with the relevant authorities, and will, promptly upon request of Foundry, or any of its successors or assigns, (and at the sole cost of Foundry or of its successors or assigns as the case may be) execute and deliver, without further compensation of any kind, any power of attorney, assignment or amendment to assignment, application for copyright, patent or other intellectual property right protection, or any other papers which may be necessary or desirable to fully secure to Foundry, its successors and assigns, all right, title and interest in and to each of the Assigned Assets, and to provide all reasonable cooperation and assistance in the prosecution of any opposition proceedings involving said rights and any adjudication of the same. Further, NHS Bradford and Sabanathan agree (subject to paragraph 2(b)) never to assert any claims, rights or moral rights in or to any of the Assigned Assets.

(b) In the event that Foundry is unable, after reasonable notice to NHS Bradford or Sabanathan, for any reason whatsoever to secure NHS Bradford's or Sabanathan's signature to any document NHS Bradford or Sabanathan is required to execute pursuant to the foregoing, NHS Bradford and Sabanathan hereby irrevocably designate and appoint Foundry and its duly authorized officers and agents, as its agents and attorneys-in-fact to act for and in its behalf and instead of NHS Bradford and Sabanathan, to execute and file any such document and to do all other lawfully permitted acts to further the purposes of the foregoing with the same legal force and effect as if executed by NHS Bradford or Sabanathan, as the case may be.

(c) As of the Effective Date hereof, Foundry shall have the sole right to make all decisions relating to the prosecution or maintenance of any patents covering the Assigned Assets, any and all expenses incurred in connection therewith shall be the sole responsibility of Foundry and shall pay Sabanathan's costs of entering into this Agreement and her agreement with Bradford NHS up to a maximum of £1,200 plus VAT payable within 30 days of the Effective Date.

(d) Foundry agrees in addition to the compensation set out in paragraph 6 to pay all Sabanathan's costs and expenses (including legal and other professional costs) properly incurred in pursuing the Entitlement Proceedings. Such payment shall be made on an indemnity basis within 14 days of application by Sabanathan.

6. Compensation.

(a) In consideration of the assignment of the Assigned Assets and the other terms and conditions hereof, Foundry will pay to NHS Bradford's Solicitors, DLA, formerly known as Dibb Lupton Alsop, on behalf of both NHS Bradford and Sabanathan for distribution as agreed between them, a total of the amount specified in paragraph 6 (b) ("the Sales Payment") below at the time indicated therein and $30,000 United States Dollars within 30 Days of the Effective Date.

(b) The Sales Payment shall be payable within three calendar months of the end of the sixth full fiscal year of Foundry following the date of the first sale of product following the first United States Food and Drug Administration approval of the product. The Sales Payment shall equal 3% of the value of net sales in countries in which a patent is granted pursuant to the Applications of Foundry and/or of any licensee and/or sub-licensee of Foundry or any successor in title of Foundry ("the Sellers") of product falling within the terms of any US patent granted pursuant to the Applications for sales during the period of the fourth, fifth, and sixth full fiscal years of Foundry following the date of the first sale of product following the first United States Food and Drug Administration approval of the product unless such percentage amounts to less than US$10,000, in which event the Sales Payment shall be zero. In any event, the Foundry shall supply NHS Bradford and Sabanathan with a statement of the sales in the period for the Sales Payment within the same period as for payment of the Sales Payment, if any, and NHS Bradford and Sabanathan shall have the right to audit such statement of sales (which audit shall be at the cost of Foundry if the Sales Payment actually made shall be 5% or more below the Sales Payment which should have been made in accordance with the provisions hereof). Sales between any of the Sellers and any associated and/or affiliated entities of such Seller shall be deemed to have been made at an arm's length price (if more than the actual price) for the purpose of the calculation of the Sales Payment.

(c) In the event that a European patent is secured on the basis of international application number PCT/GB98/00652, the Sales Payment payable under paragraph 6 (b) above shall additionally be in respect of sales in countries capable of protection under such patent, but not protected through the choice of Foundry. For the avoidance of doubt, Foundry shall not abandon any patent protection achieved in respect of the United States, United Kingdom, Germany and France before all payments under paragraph 6 (b) above have been duly made without first notifying Sabanathan and NHS Bradford and giving each of them reasonable opportunity to take over prosecution or maintenance of such protection in respect of such countries, but without otherwise affecting the terms of this Agreement.

(d) In consideration of the Report(s) described in Section 3 above, Foundry will pay the individuals responsible for preparation of the Report(s) a total of no more than $3,000 United States Dollars within thirty (30) days of receipt of the Report(s).

(e) In order to secure the making of the Sales Payment on the due date and the obligations under paragraph 7 below:

(i) Foundry shall not assign or transfer to any third party the benefit of this Agreement and/or any of the Assigned Assets and/or any of the patents granted pursuant to any of the Applications without first obtaining from such third party a binding obligation to NHS Bradford and Sabanathan to observe and perform the provisions and obligations set out herein and in particular (but without limitation) the obligation to make the Sales Payment as calculated and provided under paragraph 6 above and the obligations under paragraph 7 below; and

(ii) Foundry grants to each of NHS Bradford and Sabanathan, jointly and severally, an irrevocable power of attorney to execute such assignments and other documents as necessary to revest all rights assigned to Foundry by this Assignment and all further rights derived therefrom into the joint names of NHS Bradford and Sabanathan, which power of attorney rights may be exercised only upon the failure of Foundry (or its assignees or transferees) to make the Sales Payment and/or to comply with Section 7.

7. Branding

(a) Foundry agrees that it will and will use all reasonable endeavours to procure that the Sellers (as defined in paragraph 6) will only sell, market and otherwise exploit or promote products covered by the Applications or substantially evolving from or deriving from any of the devices covered by the Applications under a name or title which prominently features the name "Sabanathan" as part of it and which thereby recognises the Inventor.

(b) Without prejudice to paragraph 7(a) Foundry further agrees to use its reasonable endeavours to procure that any device or product which substantially derives or has evolved from any of the Technology, either solely or jointly with others bears the name "Sabanathan" as part of its title when marketed promoted sold or exploited.

8. Miscellaneous.

(a) Counterparts; Governing Law. This Agreement may be executed in any number of counterparts, each of which will constitute an original, and all of which will together constitute this one Agreement. This Agreement will be governed exclusively by English Law or, with respect to issues relating to rights under any patent, the patent laws of the jurisdiction in which the patent is pending or from which it issued.

(b) Entire Agreement. This Agreement constitutes the entire understanding and agreement between Foundry, on the one hand, and NHS Bradford and Sabanathan, on the other hand, regarding the subject matter herein, and supersedes any and all other agreements or understandings of the parties regarding such subject matter.

(c) Amendments and Waivers. Any term of this Agreement may be amended or waived only with the written consent of the parties.

(d) Notices. Any notice required or permitted by this Agreement shall be in writing and shall be deemed sufficient upon receipt, when delivered personally or by courier, overnight delivery service or confirmed facsimile, or forty-eight (48) hours after being deposited in the regular mail as certified or registered mail (airmail if sent internationally) with postage prepaid, if such notice is addressed to the party to be notified at such party's address or facsimile number as set forth below, or as subsequently modified by written notice.

(e) Severability. If one or more provisions of this Agreement are held to be unenforceable under applicable law, the parties agree to renegotiate such provision in good faith. In the event that the parties cannot reach a mutually agreeable and enforceable replacement for such provision, then (i) such provision shall be excluded from this Agreement, (ii) the balance of the Agreement shall be interpreted as if such provision were so excluded and (iii) the balance of the Agreement shall be enforceable in accordance with its terms.

(g) Advice of Counsel. EACH PARTY ACKNOWLEDGES THAT, IN EXECUTING THIS AGREEMENT, SUCH PARTY HAS HAD THE OPPORTUNITY TO SEEK THE ADVICE OF INDEPENDENT LEGAL COUNSEL, AND HAS READ AND UNDERSTOOD ALL OF THE TERMS AND PROVISIONS OF THIS AGREEMENT. THIS AGREEMENT SHALL NOT BE CONSTRUED AGAINST ANY PARTY BY REASON OF THE DRAFTING OR PREPARATION HEREOF.

(h) Payments. All payments due hereunder shall be made in U.S. Dollars ($), and shall be payable net thirty (30) days following the due date except as noted.

(i) Foundry hereby covenants with NHS Bradford and Sabanathan:

to indemnify each of NHS Bradford and Sabanathan and hold each of NHS Bradford and Sabanathan harmless in connection with any claim brought by a third party in relation to any liability caused by use of a lung occluder in accordance with the Applications or in relation to the Technology in any way; and

to indemnify NHS Bradford and Sabanathan and to hold each of NHS Bradford and Sabanathan harmless in connection with any claim from any person in relation to it having made and prosecuted the Applications and/or arising out of the Entitlement Proceedings

Schedule I

ASSIGNMENT AGREEMENT

This Assignment Agreement (this "Assignment") is made and entered into effective as of _____ by and between

The Foundry, LLC, a Delaware limited liability corporation ("Foundry"),

Bradford Hospitals NHS Trust, a Trust organized and subsisting under the laws of the United Kingdom, of Duckworth Lane, Bradford, West Yorkshire, BD9 6RY, GB ("NHS Bradford"), and

Thirumani Sabanathan, a United Kingdom citizen of 2A The Knoll, Calverley, Leeds, LS28 5FB, GB ("Sabanathan").

RECITALS

The parties hereto entered an agreement (the "Agreement") dated June_____2000 in which NHS Bradford and Sabanathan agreed to assign their respective right, title and interest in and to Technology (as defined in the Agreement), and other related rights, to Foundry.

NOW THEREFORE, the parties hereby agree as follows:

1. Definition of Assigned Assets. As used herein, "Assigned Assets" means:

(a) The Technology, which is defined as information, trade secrets, know-how, intellectual property rights, clinical information, prototypes, or test data related to devices, systems, methods, or procedures for bronchial occlusion for isolation of diseased sections of lungs. Any information, prototypes, or other work in the field of this procedure performed directly by the late Dr. Sabanathan or by any associates, consultants, or related companies also constitutes the Technology.

(b) All worldwide patents, patent applications, patent rights, copyrights, copyright registrations, moral rights, trade secrets, know-how, mask work rights, rights in trade dress and packaging, and goodwill directly relating to the Technology, whether arising under the laws of the United Kingdom, the United States of America or the laws of any other state, country or jurisdiction existing at the dare of this Agreement. This includes the pending United Kingdom patent application number 9708681.3 and the international application number PCT/GB98/00652 ("the Applications") and any additional, continuation, continuation-in-part, or division thereof or any substitute application therefore, any reissue, extension, or patent term extension of any such patent, and any foreign counterpart of the foregoing.

(c) All documentation, drafts, papers, designs, schematics, diagrams, models, prototypes, source and object code (in any form or format and for all hardware platforms), computer-stored data, diskettes, manuscripts and other items describing all or any part of the Technology or any information related thereto or in which all or any part of the Technology, any intellectual property right or such information is set forth, embodied, recorded or stored existing at the date of this Agreement.

2. In consideration of the Agreement, and subject to its terms which are hereby incorporated in this Assignment, NHS Bradford and Sabanathan hereby sell, assign, transfer, release, quitclaim and convey to Foundry, NHS Bradford's and Sabanathan's entire right, title and interest in and to each and all of the Assigned Assets. Without limiting the foregoing, NHS Bradford and Sabanathan hereby assign all their respective right, title and interest in and to the Applications; and all their respective right to file or prosecute patent applications covering the Assigned Assets in any jurisdiction in the world.

IN WITNESS WHEREOF, the undersigned have executed this Assignment effective as of the date and year first above written.

THE FOUNDRY, LLC

By: _____

Name: Hanson S. Gifford, III

Title: President

Address: The Foundry, LLC
604-D Fifth Avenue,
Redwood City, CA 94063
USA

BRADFORD HOSPITALS NHS TRUST

By: _____

Name: _____

Title: _____

Address: Duckworth Lane
Bradford
West Yorkshire, BD9 6RY
United Kingdom

THIRUMANI SABANATHAN

By: _____

Address: 2A The Knoll,
Calverley,
Leeds,
West Yorkshire, LS28 5FB
United Kingdom

IN WITNESS WHEREOF, the undersigned have executed this Agreement effective as of the date and year first above written.

THE FOUNDRY, LLC

By: _____

Name: Hanson S. Gifford, III

Title: President

Address: The Foundry, LLC
604-D Fifth Avenue,
Redwood City, CA 94063
USA

BRADFORD HOSPITALS NHS TRUST

By: David Jackson

Name: DAVID JACKSON

Title: CHIEF EXECUTIVE

Address: Duckworth Lane,
Bradford,
West Yorkshire, BD9 6RY
United Kingdom

THIRUMANI SABANATHAN

By: T Sabanathan

Address: 2A The Knoll,
Calverley,
Leeds,
West Yorkshire, LS28 5FB
United Kingdom

IN WITNESS WHEREOF, the undersigned have executed this Agreement effective as of the date and year first above written.

THE FOUNDRY, LLC

By: _____

Name: Hanson S. Gifford, III

Title: President

Address: The Foundry, LLC
604-D Fifth Avenue,
Redwood City, CA 94063
USA

BRADFORD HOSPITALS NHS TRUST

By: _____

Name: DAVID JACKSON

Title: CHIEF EXECUTIVE

Address: Duckworth Lane,
Bradford.
West Yorkshire. BD9 6RY
United Kingdom

THIRUMANI SABANATHAN

By: _____

Address: 2A The Knoll.
Calverley.
Leeds.
West Yorkshire. LS28 5FB
United Kingdom

DATED 2000

(1) BRADFORD HOSPITALS NHS TRUST

- and -

(2) THIRUMANI SABANATHAN

AGREEMENT

THIS AGREEMENT is dated this ___ day of _____ 2000

BETWEEN

(1) **BRADFORD HOSPITALS NHS TRUST,** a United Kingdom Trust of Duckworth Lane, Bradford, West Yorkshire, BD9 6RY (**"the Hospital"**) of the first part; and

(2) **THIRUMANI SABANATHAN,** a United Kingdom citizen of 2A The Knoll, Calverley, Leeds, LS28 5FB (**"Sabanathan"**) of the second part.

WHEREAS

A Sabanathan is the successor in title to the entire right and interest of Sabaratnam Sabanathan (Deceased) (the "Inventor"), a former employee of the Hospital, in and to an invention made by him and entitled "Occlusion Device" ("the Invention"), the subject of British patent application number 9708681.3 filed 30 April 1997 and International patent application number PCT/GB98/00652 filed 03 March 1998 (together "the Applications") by virtue of a grant of probate dated 9th October 1997 of the will of the Inventor pursuant to which Sabanathan is the only beneficiary and person entitled.

B The Hospital claimed ownership of the invention by virtue of its employment of the Inventor and is the applicant (with the exception of the United States of America) for the Applications.

C Sabanathan disputes the Hospital's claim to ownership of the invention and intends to file an application ("the Entitlement Application") in the United Kingdom Patent Office under Sections 8 and 12 of the Patents Act 1977.

D The parties have agreed to submit under Section 82(6) of the Patents Act 1977 to the jurisdiction of the United Kingdom courts and the Hospital has agreed not to contest such Entitlement Application under and subject to the terms of this Agreement.

It is therefore hereby agreed as follows:

AGREEMENT

1. Within 60 days of the date hereof Sabanathan shall file the Entitlement Application under Sections 8 and 12 of the Patents Act 1977 questioning the entitlement of the Hospital to be

granted patents in the United Kingdom and elsewhere on the basis of the Applications and on the ground that the inventor was not employed to make inventions and that Section 39 of the Patents Act 1977 does not apply to him. Sabanathan shall seek a ruling that the Applications should proceed in her name alone.

2. In consideration of the sum of £1 (ONE POUND STERLING) Sabanathan shall execute, when requested to do so by the Hospital, an assignment in the form set out in Schedule I hereto or in such other form as the parties shall agree.

3. In consideration of the Hospital not contesting the Entitlement Application and the Hospital complying with the terms of this Agreement Sabanathan covenants that she will not take any action against the Hospital or any of its officers, employees or advisors in connection with their making and/or prosecution of the Applications (or either of them) and/or in connection with the advice given or received thereon , that she hereby agrees to waive all and any claims and/or causes of action against the Hospital or any of its officers, employees or advisors arising therefrom or in connection therewith and that she hereby releases the Hospital and each of its officers, employees or advisors from all and any such claims and/or causes of action and/or any liability resulting therefrom. The parties acknowledge their joint intention that each of such officers, employees and/or advisors shall be entitled to the benefit of the covenant set forth herein.

4. The proceeds of any transfer or exploitation of the Invention the Application and or any rights thereunder shall be shared equally between the parties hereto net of any costs and expenses agreed by the parties

5. The Hospital covenants with and to Sabanathan that it has not and will not enter into any agreement with any party relating to or associated with the Invention or the Applications without making full and complete disclosure to her prior to entering into such agreement.

6. Sabanathan hereby warrants to the Hospital that she is the successor in title to the entire right and interest of the Inventor in and to the Invention.

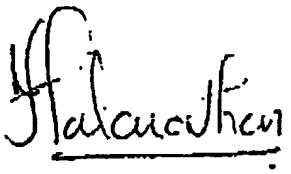
7. Each party acknowledges that, in executing this Agreement, such party has had the opportunity to seek independent legal advice, and has read and understood all of the terms and provisions of this Agreement. This Agreement shall not be construed against any party by reason of the drafting or preparation hereof.

9. This Agreement supersedes any previous agreement between the parties in relation to the Invention and the Applications.

IN WITNESS of which the parties have executed this Agreement as follows:

SIGNED by)
for and on behalf of **BRADFORD**)
HOSPITALS NHS TRUST)

SIGNED by **THIRUMANI**)
SABANATHAN)
)



SCHEDULE I

DATED **2000**

(1) THIRUMANI SABANATHAN

- and -

(2) BRADFORD HOSPITALS NHS TRUST

ASSIGNMENT

THIS ASSIGNMENT is dated this ____ day of _____ 2000

BETWEEN

(1) THIRUMANI SABANATHAN, a United Kingdom citizen of 2A The Knoll, Calverley, Leeds, LS28 5FB ("Assignor"); and

(2) BRADFORD HOSPITALS NHS TRUST, a United Kingdom Trust of Duckworth Lane, Bradford, West Yorkshire, BD9 6RY ("Assignee").

WHEREAS

A The Assignor is now the proprietor of British patent application number 9708681.3 and International patent application number PCT/GB98/00652 (together "the Applications") and is the beneficial owner of the invention entitled "Occlusion Device" ("the Invention") by virtue of a decision of the Comptroller of the Patent Office dated _____.

B By virtue of the Agreement dated _____ (the "Agreement") between the parties, Sabanathan agreed to enter this Assignment of a part share of the Invention to the Hospital.

It is therefore hereby agreed as follows:

AGREEMENT

9. In consideration of the covenants given pursuant to clause 4 of the Agreement by the Assignee to the Assignor the Assignor hereby assigns with full title guarantee absolutely to the Assignee free of all liens, charges and encumbrances thereon a half share in her right, title and interest in and to each of the Applications and in and to the right to make a new application or applications whether divisional, continuation or continuation-in-part application or applications, in respect of any part or parts of each of the Applications and in the right to claim priority from the Applications pursuant to any convention or law (including without limitation the Paris Convention (as amended)) to the intent that the grant of any patents or similar protection shall be in the joint names of and shall vest in the Assignee and the Assignor jointly as tenants in common in equal shares.

10. The Assignor undertakes that she will, at the request and at the expense of the Assignee, do all acts and execute all documents which may be necessary or desirable both to secure the

vesting in the Assignee of the property and rights assigned to the Assignee hereunder and to assist in the resolution of any issues arising concerning any future applications claiming priority from the Application.

11. It is certified that this transaction does not form part of a larger transaction, or series of transactions, in respect of which the amount or value, or the aggregate amount or value, of the consideration involved exceeds sixty thousand pounds (£60,000).

12. This Assignment shall be governed by, and construed in accordance with, English law and the parties hereby submit to the exclusive jurisdiction of the English courts.

IN WITNESS of which the parties have executed this agreement as follows:

SIGNED by THIRUMANI SABANATHAN)
)
)

SIGNED by)
for and on behalf of BRADFORD)
HOSPITALS NHS TRUST)

IN THE MATTER OF AN APPLICATION UNDER SECTIONS 8(1)(a) AND 12(1)(a) PATENTS ACT 1977 BY THIRUMANI SABANATHAN

STATEMENT OF CASE

1. This is an application by Thirumani Sabanathan ("the Applicant") under Sections 8(1)(a) Patents Act 1977 in respect of three patent applications, namely United Kingdom Patent Application No 9708681.3 ("the British"), International Patent Application No PCT/GB98/00652 ("the International"), and European Patent Application No 98908220.1 ("the European"), together referred to as "the Applications" for the same invention ("the Invention") relating to a Lung Treatment Device.

2. The British was filed on 30 April 1997 and published under the number 2324729 on 04 November 1998. The British application was filed in the name of Bradford Hospitals NHS Trust a United Trust set up under the Bradford Hospitals National Health Service Trust (Establishment) Order 1990 ("the Hospital") identifying, shortly after filing, the sole inventor Sabaratnam Sabanathan ("the Inventor"), a British subject resident at that time at 8 Foster Park Road, Denholme, Bradford, United Kingdom. The British is currently pending in the United Kingdom Patent Office, examination having been requested on 23 October 1998.

3. The Inventor died on 29 April 1997 and the present application is made by his widow and sole heir (by virtue of a Grant of Probate dated 09 October 1997 of the will of the Inventor).

4. The International was filed on 03 March 1998 in the joint names of the Hospital and the Applicant, although for the United States the Applicant was sole applicant. The Applicant consented to the filing of the International by executing a Power of Attorney in favour of the agent, Mr Mark Lunt of Dibb Lupton Alsop. The International was published under the title "Occlusion Device" under the number WO98/48706, a copy is attached as Appendix 1.

5. The Applicant was at all material times unaware of the identification made of applicants in the International and did not know she was identified as applicant for the United States. She was not given a copy of WO98/48706.

6. The European is the regional phase of the International, but was not entered in due time in the European Patent Office ("EPO") and has now been treated as withdrawn.

7. No national or regional phases of the International were filed by the due date of 20 October 1999 (or 30 November 1999 in the case of the EPO and some other territories).

8. The Inventor was employed by the Hospital as a consultant surgeon in Thoracic Surgery in 1989 and a copy of his Job Description is attached as Appendix 2. There is no requirement for him to conduct research. His time is to be devoted to patient care and teaching. All the research that

the Inventor did undertake he did so in his own time. His job at all material times was to treat patients to the best of his technical ability and to pass on his skills to others. The position is consistent with the findings in Greater Glasgow Health Board's application: 1996 RPC 207 in which it was held that improving patient care was not the same as being employed to invent.

9. Consequently, it is submitted that the Hospital should not unilaterally have claimed ownership of the Invention by marking itself an applicant by virtue of Section 39(1)(a) of the Patents Act 1977, if that is what it has done.

10. As well as being employed by the Hospital, the Inventor also had his own private practice in which he was self-employed. It was in the course of his private work that he made the Invention and he had no special obligation to further the interests of the Hospital. Consequently, the Hospital should not have claimed ownership of the Invention under Section 39(1)(b) Patents Act 1977 if that is what it has done.

11. Although the Hospital filed the Applications at no time did the Inventor agree that the Invention was to be owned, even in part, by the Hospital. In the relevant correspondence there is no mention of the Hospital owning Invention or any part of it. See his letter of 11 April 1997 to Mr Lunt Appendix 3; Mr Lunt's reply of 23 April 1997 Appendix 4; and the Inventor's response of 25 April 1997 Appendix 5. He was of the view that some accommodation with the Hospital would be reached in the end. He also had support for his view on this from colleagues in the Hospital. See Dr Richardson's letter to Mr Lunt dated 02

May 1997 Appendix 6 following Mr Lunt's letter of 30 April 1997.

12. He may have thought that as the Hospital acknowledged his inventorship this was an acknowledgement of his ownership of the Invention.

13. After the Inventor died, the present Applicant permitted the Hospital to take the lead in developing the idea commercially. She believed that the Hospital and their patent attorneys Dibb Lupton Alsop would keep her informed of developments.

14. However, in October 1999 the Hospital evidently decided not to proceed further with the Applications and as a result the International application terminated without national or regional phase entry in any of the originally designated countries. Consequently, the European application was deemed withdrawn. The Applicant was not informed. The Applicant was also not informed when the European Patent Office sent its notices to the registered applicant in connection with the European application under rules 85(a)(1) and (b) European Patent Convention.

15. The first knowledge that the Applicant had that the International had lapsed was when she was approached in February 2000 by Mr Hanson Gifford of The Foundry, a US Limited Liability Company incorporated in Delaware. Mr Gifford expressed an interest in the Invention, but explained that, according to the Hospital's patent attorneys, the European and the International were deemed withdrawn.

16. Following negotiations with the Hospital and the Foundry the Applicant has decided to seek an order that the Invention belongs solely to her through her husband's (the Inventor's) estate.

17. Accordingly it is requested that the Comptroller order as follows:

    a) that, under Section 7(2)(a) Patents Act 1977, the Invention belongs solely to the Applicant and Section 39(1)(a) or (b) Patents Act 1977 do not apply;

    b) that, under Section 8(2)(a) Patents Act 1977, the British application should proceed henceforth in the sole name of the Applicant;

    c) that, under Section 12(1)(a) Patents Act 1977, the International application and such rights as may remain in it for the purpose of entering the national phase thereof in any country designated in the International application (excepting countries designated via the European Patent Office) shall belong and shall be deemed always to have belonged solely to the Applicant; and

    d) that under Section 12(1)(a) Patents Act 1977, the European application and such rights as may be provided by the European Patent Convention under Articles 60 and 61 thereof to persons adjudged to be entitled to the grant of a European patent, shall belong solely to the Applicant.

Dated this _____ day of _____ 2000

By Bailey Walsh & Co
Agents for the Applicant

PATENTS ACT 1977

IN THE MATTER of UK patent application No. 9708681.3, International patent application No. PCT /GB98/00652 and European patent application No. 98908220.1 in the name of Bradford Hospitals NHS Trust

and

a reference under sections 8(1)(a) and 12(1)(a) by Thirumani Sabanathan

DECISION

Introduction

1. The invention to which these applications relate is an obturator for insertion into a bronchial tube or tubule of a lung to seal against the passage of fluids. The device is intended for use in the treatment of emphysema by preventing air from being drawn into the blocked hyper-inflated alveoli which are a characteristic of this disease, thus allowing them to deflate and relieve pressure on neighbouring alveoli. It can also be used in cases of bleeding into the lung to confine the blood to a restricted area and prevent it from being spread by coughing.

2. UK Patent application No. 9708681.3 was filed in the name of Bradford Hospitals NHS Trust ("the Hospital") on 30 April 1997. It was published as No. GB 2324729 A on 4 November 1998 and is currently undergoing substantive examination. No patent has yet been granted. Form 7/77 filed on 15 May 1997 identifies Sabaratnam Sabanathan as inventor and states that the right to be granted a patent is derived "by virtue of the employment of the inventor by the Applicant".

3. International application No. PCT/GB98/00652 under the Patent Cooperation Treaty was filed on 3 March 1998 with a claim to priority from the above UK application. It names the Hospital as applicant for all designated States except the US, and the present referrer, Thirumani Sabanathan as applicant for the US only, by virtue of being heir of the deceased inventor. The international application was published as No. WO 98/48706 A1 on 5 November 1998.

4. European application No. 98908220.1 is the application which arises from the designation of a European patent in the international application.

5. The statement of case was filed in the name of the referrer on 7 September 2000, seeking to establish that the invention belonged solely to her through the estate of her husband, the inventor, and asking the comptroller to make certain orders as a consequence. The patent agents acting for the Hospital wrote to the Patent Office on 1 December 2000 stating:

> *"Bradford NHS Trust does not dispute the reference under Sections 8(1)(a) and 12(1)(a) filed by the inventor's widow in the circumstances of the present case. Accordingly, no counter-statement will be filed. The hospital had understood that the reference was going to be filed from the requests for copies of correspondence etc. from our file, with which the hospital had co-operated."*

6. I take it therefore that the facts upon which Mrs Sabanathan relies in her statement represent common ground between her and the Hospital. Accordingly, it falls to me to decide, on the balance of probabilities, whether the case she sets out in the statement and the documents filed with it is sufficient to establish her entitlement to the invention.

The referrer's case

7. The course of events as they appear from the statement is that the inventor, Mr Sabanathan, had been employed by the Hospital as a consultant in thoracic surgery in 1989 but also had a private practice in which he was self-employed. He died suddenly on 29 April 1997, one day before the filing of the initial UK application, No. 9708681.3.

8. After her husband died, Mrs Sabanathan allowed the Hospital to take the lead in developing the invention commercially, believing that she would be kept informed of progress, either by the Hospital or by their patent agents Dibb Lupton Alsop. On 31 March 1998 she executed a power of attorney appointing Mr Mark Lunt of Dibb Lupton Alsop as agent for the purposes of the international application which had recently been filed.

9. Mrs Sabanathan thereafter heard nothing further until February 2000, when she was approached by a representative of The Foundry (a US company) who expressed interest in the

invention but explained that according to the Hospital's patent attorneys, the international application and the European application arising under it were deemed withdrawn. It appeared that the international application had been allowed to lapse without entering the national or regional phase in any of the designated States. Mrs Sabanathan made the present reference following negotiations with the Hospital and The Foundry.

10. Mrs Sabanathan's arguments can be summarised as follows:

- Mr Sabanathan was employed by the Hospital to care for patients and to teach; there was no requirement for him to conduct research. Therefore consistent with the decision of the Patents Court in *Greater Glasgow Health Board's Application* [1996] RPC 207 the Hospital could not claim ownership of the invention under section 39(1)(a) of the Act.

- He made the invention in the course of his private work and had no special obligation to further the interests of the Hospital, who could not therefore claim ownership under section 39(1)(b).

- He had at no time agreed that the invention was to be owned either wholly or in part by the Hospital.

In support of the first two of these arguments there has been filed a copy of a job description for Mr Sabanathan's post with the Hospital. In support of the third there has been filed correspondence between Mr Sabanathan and Mr Lunt during the period from 23 to 30 April 1997, and a letter dated 2 May 1997 from Mr Sabanathan's colleague Mr Richardson informing Mr Lunt of Mr Sabanathan's death.

Analysis

11. The first two of Mrs Sabanathan's arguments turn on section 39 of the Act, the relevant portion of which reads:

> *" (1) Notwithstanding anything in any rule of law, an invention made by an employee shall, as between him and his employer, be taken to belong to his employer for the purposes of this Act and all other purposes if -*

(a) it was made in the normal course of duties of the employee or in the course of duties falling outside his normal duties, but specifically assigned to him, and the circumstances in either case were such that an invention might reasonably be expected to result from the carrying out of his duties; or

(b) the invention was made in the course of the duties of the employee and, at the time of making the invention, because of the nature of his duties and the particular responsibilities arising from the nature of his duties he had a special obligation to further the interests of the employer's undertaking.

(2) Any other invention made by an employee shall, as between him and his employer, be taken for those purposes to belong to the employee."

12. As I have explained above Mrs Sabanathan's arguments are not contested by the Hospital. If this is indeed the truth of the matter, then clearly under section 39 the invention belonged to Mr Sabanathan rather than the Hospital. However, I believe that before coming to this conclusion I should consider the matter in the light of the job description for Mr Sabanathan's post with the Hospital, which was filed with the statement.

13. I observe that this does not on the face of it appear to be a contractual document. From the matter at the foot of page 4 referring to subsequent interviews it would seem to a copy of a document sent to prospective interviewees. Nevertheless, in the absence of any contest of the matter by the Hospital, I am satisfied that it does indeed define and describe the duties which the Hospital required Mr Sabanathan to perform.

14. Turning to what appear to me to be the relevant parts of this document, sections 1 and 2 state that the post is for a Consultant in Thoracic Surgery to be based at Bradford Royal Infirmary, and its purpose is stated in section 4 to be "To join the Consultant Surgeon in post to provide comprehensive Thoracic Surgery services to the catchment population of approximately 1 million". The duties of the post are listed as items (i) to (vii) in section 7.

15. Items (i) to (v) deal with surgical services, emergency hospital cover, out-patient clinics, surgical audits, and advice to other consultants, and are matters which the postholder *will* provide. Item (vi) *expects* the postholder to participate in certain regional cardiothoracic

meetings and post-graduate training programmes. Research is covered by the final item, (vii), which (emphasis added) states:

> *"It is hoped that the appointee will promote and initiate research in Thoracic Surgery".*

A provisional time-table follows, allocating time under the headings Management, Teaching, Surgical Audit, Ward Round, Operating and Clinic. No mention is made of study or research, and only alternate Friday afternoons are left free.

16. Some further guidance as to the relevant importance of research in relation to the other duties can be gleaned from the following statements elsewhere in the document:

> *"Consultants have a primary role to provide clinical services to patients referred to them."* (Section 6 lines 5-6 :Consultants relationship with Health Authority and General managers.)
>
> *"The University of Bradford has a Department of medical and Surgical Sciences and makes its laboratory facilities available to Consultants engaged in research projects."* (Section 8 lines 5-8: Postgraduate and Research.)
>
> *"Research funds are available in competition with other bids from the Regional Health Authority."* (Section 10 lines 3-4: Developments.)

17. In the light of the judgment of Jacob J in *Greater Glasgow Health Board's Application* [1996] RPC 206, to which the referrer draws attention, I think it is clear that the Hospital did not in reality engage Mr Sabanathan to carry out research, and did not expect an invention to result from the carrying out of his duties. Unlike the other listed duties, the "duty" to carry out research is expressed merely in terms of hope rather than obligation or expectation. I do not think the Hospital were doing anything more than giving Mr Sabanathan an opportunity to engage in research if he wished, in such time as he could spare from his primary duties relating to patient care, teaching and management .

18. Thus, in the *Greater Glasgow* case the inventor was employed as a hospital registrar on terms which included expectations, not listed as part of the specific duties of the contract, that he would engage in teaching and research. Whilst involved in private study at home he made an

invention which enabled him to do his job better. As Jacob J. put it at page 222 lines 24-34:

> *"One gets a very clear picture of what the doctor was doing. He was doing some teaching, and any professional man in his position would be taking an interest in research so far as it was possible consistent with his primary and essential function of treating patients.*
>
> *Dr Montgomery made the invention in his own time, actually when he was preparing for some further examinations. He was not treating a patient. He was considering the problem of eye examination generally.*
>
> *I have come to the very, very clear conclusion that when he made that invention he was not acting in the course of his normal duties as a registrar."*

and at page 223 lines 17-22, construing the second limb of section 39(1)(a) in the light of *Harris' Patent* [1985] RPC 19:

> *"Falconer J pointed out that the circumstances referred to were not the general circumstances of employment but the particular circumstances surrounding the making of the invention.... The particular circumstances in which this invention was made were nothing to do with Dr Montgomery carrying out his duties. He was at home. He was doing his exams."*

19. It being common ground that the invention was made in Dr Sabanathan's own time, the circumstances are on all fours with *Greater Glasgow*. Indeed they favour the inventor even further in that there is merely a "hope" - not even an "expectation" as in *Greater Glasgow* - that research will be carried out. Whilst I accept that, unlike *Greater Glasgow*, the hope is expressed as a duty, I do not think that affects the underlying reality.

20. That suffices to dispose of the argument under section 39(1)(a). However, I am referred also to section 39(1)(b), which was not in issue in *Greater Glasgow*, and this refers to inventions made in the course of the "duties", as distinct from the "normal duties" of the employee. Nevertheless I consider my reasoning above to apply equally to the first limb of section 39(1)(b). This suffices to dispose also of the argument under this subsection, and I do not need to consider its second limb, namely whether Mr Sabanathan was acting under a special obligation to further the interests of his employer's undertaking when he made the invention.

21. I am therefore satisfied that under section 39 the invention belonged to Mr Sabanathan and not the Hospital. It follows that the Hospital were not entitled to claim ownership by virtue of their employment of the inventor. I now turn to the question underlying the third of Mrs Sabanathan's arguments, namely whether there had been any agreement by the inventor that the invention was to be owned by the Hospital.

22. The correspondence which Mrs Sabanathan has put forward is in fact silent in the matter of ownership. It is concerned largely with the drafting of the patent specification and whether others besides Mr Sabanathan were entitled to claim inventorship. It is perhaps surprising that, if the Hospital did own the invention, Mr Lunt was corresponding directly with Mr Sabanathan in this way. In paragraph 12 of the statement it is surmised that Mr Sabanathan may have assumed that the acknowledgement of his inventorship by the Hospital was tantamount to an acknowledgement of his ownership. It seems all too likely that the ownership issue was never clearly resolved between the Hospital and Mr Sabanathan before his death.

23. There is therefore nothing before me to suggest a transfer of ownership from Mr Sabanathan to the Hospital, and displace the operation of section 39 in Mr Sabanathan's favour. Indeed the Hospital have not disputed Mrs Sabanathan's argument that there was no such transfer.

Findings and Orders

24. I find that therefore that the invention belonged to Mr Sabanathan by virtue of section 39(2) of the Act, and was not transferred to the Hospital. Although it is not made clear in the extract from the probate documents which were filed with the reference, I accept that his widow Mrs Sabanathan is his heir at law, and I find that she has the right to be granted a UK patent as his successor in title under section 7(2)(c) of the Act.

25. I therefore order that under section 8(2)(a) of the Act, UK patent application No. 9708681.3 should henceforth proceed solely in the name of the referrer, Thirumani Sabanathan.

26. Mrs Sabanathan has asked for orders to be made under section 12(1)(a) that she is entitled to the international application and such rights as remain in it for the purposes of entering the

national phase in any designated State (except those designated via the European route); and to the European application and such rights as may be provided under Articles 60 and 61 of the European Patent Convention to persons entitled to grant. However, both these applications may now fall to be treated as withdrawn through failure of the international application to enter any regional or national phases within the prescribed periods (although I note that the European Patent Office register shows the European application as still subsisting). If so, the decision as to whether the applications can be revived to allow a patent to be granted is one for each of the national and regional authorities before which Mrs Sabanathan wishes to proceed, and is not within my power to make. Whilst section 12 gives me a power to make such order as I think fit to give effect to my determination on entitlement, any such order will be subject to the appropriate national or regional law, and may be of limited effect.

27. Under section 12(1)(a,) I therefore merely declare that according to United Kingdom law the invention of international application No. PCT/GB98/00652 belonged to Sabaratnam Sabanathan and not to his employer Bradford Hospitals NHS Trust, and no rights in any patent application were transferred to the latter. It will then be open for Mrs Sabanathan as Mr Sabanathan's successor in title to produce this declaration in any designated State or region in which she wishes to proceed.

28. I note that section 12(6)(c) gives the comptroller power to order a new UK application to be made in a case where a published international application is withdrawn. However a UK application is still in being and I therefore make no order under this subsection.

29. As regards the European patent application, section 12(3) says that in its application to European patents section 12 is subject to section 82, which by virtue of section 82(3) applies to a question arising before grant of a European patent whether a person has the right to be granted a European patent or a share in such patent. By virtue at least of the fact that the Hospital has its principal place of business in the United Kingdom, I have a jurisdiction to determine that question under section 82(4) or 82(5) (depending upon whether or not it is construed as an employer-employee question). Section 82(8) allows me to make an order under section 12.

30. Having regard to my findings above, I therefore declare that under Article 60 EPC the right to a European patent arising from European application No. 98908220.1, insofar as it still subsists and including any rights arising in consequence under Article 61 EPC, belongs solely to Thirumani Sabanathan as successor in title to the inventor Sabaratnam Sabanathan.

Costs

31. Neither party has asked for costs and I make no award.

Appeal

32. This not being a matter of procedure, the period for appeal is six weeks.

Dated this 25th day of January 2001

G M Bridges

G M BRIDGES

Divisional Director, acting for the Comptroller

PATENT OFFICE 2nd

THE PATENT OFFICE

GREATER GLASGOW HEALTH BOARD'S APPLICATION

Chancery Division (PATENTS COURT)

[1996] RPC 207

HEARING-DATES: 5 October 1995

5 October 1995

CATCHWORDS:

Patent Application -- Ownership -- Entitlement dispute -- Employee-inventor -- Registrar at hospital -- Whether invention made in the course of his employment -- Whether duties extended beyond clinical duties to research -- Whether invention reasonably expected to result from his duties -- Patents Act 1977, sections 12(1)(b), 39(1), (2), 42(2).

HEADNOTE:

This was an application by the inventor M, for an order that international application No PCT/GB9O/00465 filed in the name of his employer, the Greater Glasgow Health Board, and all national applications resulting from it should proceed in his name alone.

In 1988 M made an invention relating to an optical spacing device for use with an indirect ophthalmoscope. It was common ground that at the time of making the invention he was employed as a Registrar in the Department of Ophthalmology at the Western Infirmary Tennent Institute. Some staff at the Institute were paid by Glasgow University and had clinical appointments, some were paid by the Health Board and had honorary University appointments while others were paid in part by the University and in part by the Health Board. M was paid by the Health Board. The Institute provided a research facility that was in effect a support unit common to both the Infirmary and the University, although the emphasis towards research was biased towards the University. It was also common ground that M had conceived the original idea for the invention not during clinical work but while he was involved in private study at home. M and the Health Board agreed that a patent application would be filed by the Health Board on the understanding that a joint referral would be made to the Comptroller to determine who was entitled to the rights in the invention.

M's job description stated that his duties were clinical responsibilities in the out-patient department and in casualty and ophthalmic and general care of in-patients including ophthalmic surgery. In practice M was working just over 80 hours a week in the exercise of his clinical responsibilities. The job description also included a number of other items not described as duties including participation in the undergraduate and postgraduate teaching of ophthalmology. He was also "expected to avail himself of the facilities provided" for basic and clinical research. The evidence of his head of department was that M was not contracted to do research but that he was able, if he wished to become involved with the University side of the Institute, to further his career by contributing to the University's teaching and research programme. M argued that he was not employed to invent and that the rights in the invention belonged to him.

The Health Board claimed that the purpose of the Institute's research facility was to seek improvement in the treatment and diagnostic care of patients; that the duties of a doctor in M's position in assessing and treating patients included seeking to overcome any problems encountered in their treatment including problems involving ophthalmic equipment which was either not performing satisfactorily or was in some way inadequate.

The Hearing Officer held that the rights in the invention belonged to the Health Board on the basis that whilst research may not have been a regular feature of M's work it was a facility to which someone in his position with responsibilities to patients would need to turn in the normal course of his work and accordingly the making of the invention was connected with M's primary duties as a clinician. M appealed to the Patents Court.

Held, allowing the appeal:

(1) It was a fallacy to assume on the basis that M's duty was to treat patients that it extended to devising new ways of diagnosing and treating patients.

(2) The particular circumstances of M making the invention had nothing to do with the carrying out of his duties. Whilst M's invention might be a useful accessory to his contracted work it was not really part of it.

Harris' Patent [1985] RPC 19 and Stephenson, Jordan & Harrison v MacDonald & Evans (1952) 69 RPC 10 referred to.

Observed:-

Doctors frequently devise new and better treatments. Some of those will involve patentable inventions. Most doctors are employed. If, just because they are employed and because the invention could be used for the purpose of their employment, the invention belongs to the employer then many doctors would be placed in a very difficult position -- "Can they publish what they have devised?", "Do they have to get their employer's permission to publish?" At present they do not. I do not see why they should in the future.

CASES-REF-TO:
Electrolux Ltd v Hudson [1977] FSR 312
Patchett v Sterling Engineering Co Ltd (1955) 72 RPC 50

INTRODUCTION:

PJ Herbert:- The application in suit was filed on 29 March 1990 in the name of the Greater Glasgow Health Board (the GGHB) with a priority date of 30 March 1989 based on GB application number GB8907156.7. The application names Dr Montgomery as the sole inventor and relates to an optical spacing device for use with an indirect ophthalmoscope which allows accurate localisation of the image of the retina in three-dimensions so that measurements relative to anatomical features of the retina can be carried out. The stated object of the invention is to mitigate certain disadvantages experienced with existing measuring equipment and to provide a device with which quantitative measurements of the retina can be made.

The reference under section 12 was filed on 17 July 1991 in the name of Dr Donald Mitchell Inglis Montgomery seeking relief in the form of an order that the International Patent Application and any national applications resulting from the International Application shall proceed solely in the name of Dr Montgomery or such other relief as the Comptroller may direct. After the completion of the usual rounds of evidence, the matter came before me at a Hearing on 19 July 1994.

Evidence for the referrer is given by Dr Montgomery himself, Professor Foulds who, at the time of the invention, was Head of Department at the Tennent Institute of Ophthalmology, Angus MacCuish, Consultant Physician in charge of the Diabetic Centre at the Glasgow Royal Infirmary, and John Macfarlane and Ian Irving who are respectively Senior Medical and Medical Technical Officers at the Tennent Institute of Ophthalmology. Evidence for the GGHB is given by Dr George Forwell (Chief Administrative Medical Officer and Director of Public Health of GGHB), Dr John Rowan (Deputy Director of Department of Clinical Physics and Bio-Engineering), Charles Fleming (Assistant Director of Planning and Commercial Development at GGHB), Simon Skinner (Head of Patent Services at GGHB and former Assistant Director of Administration), Fergus Neil (Director of the Industrial and Commercial Development Service of the University of Glasgow), Michael Cleary (former Director of Administration at GGHB), Robert Naismith (partner in the firm of Cruikshank & Fairweather, Chartered Patent Agents), and Donald Allen (employed as a senior physicist by GGHB at the time of the invention).

There is no dispute between the parties that Dr Montgomery is the sole inventor of the optical spacing device and that at the time of making the invention he was employed by the GGHB. A substantial part of the evidence from both sides relates to correspondence, discussions and negotiations between Dr Montgomery and the GGHB leading up to, and subsequent to, the filing of the patent application and to the possible sharing of potential profits resulting from exploitation of the invention. The matter I have to decide, however, is whether the application in suit belongs to Dr Montgomery or to the GGHB having regard to the requirements of sections 39(1) and 39(2) of the Act which state:

"Section 39(1)

Notwithstanding anything in any rule of law, an invention made by an employee shall, as between him and his employer, be taken to belong to his employer for the purposes of this Act and all other purposes if --

(a) it was made in the course of the normal duties of the employee or in the course of duties falling outside his normal duties, but specifically assigned to him, and the circumstances in either case were such that an invention might reasonably be expected to result from the carrying out of his duties; or

(b) the invention was made in the course of the duties of the employee and, at the time of making the invention, because of the nature of his duties and the particular responsibilities arising from the nature of his duties he had a special obligation to further the interests of the employer's undertaking.

Section 39(2)

Any other invention made by an employee shall, as between him and his employer, be taken for those purposes to belong to the employee."

It was common ground between counsel that section 39 is declaratory of the situation which existed under common law prior to the coming into force of the 1977 Act and that, in the circumstances of the present case, the alternative set out in section 39(1)(a) is not applicable, that is that there is no question of Dr Montgomery having made the invention in the course of duties falling outside his normal duties but specifically assigned to him. The matter in dispute therefore is whether Dr Montgomery made the invention in the course of his normal duties in circumstances such that an invention might reasonably be expected to result in accordance with section 39(1)(a) or whether, at the time of making the invention, he had a special obligation to further the interests of the employer's undertaking in accordance with section 39(1)(b). If neither of these requirements is satisfied, then the invention belongs to Dr Montgomery by virtue of section 39(2).

At the time when the invention was conceived Dr Montgomery was employed by GGHB as a Registrar in the Department of Ophthalmology at the Western Infirmary, Tennent Institute. His duties, which are set out in his original offer of employment and job description to which I will return later, were primarily of a clinical nature concerning the assessment and treatment of patients and any teaching and research activities it was agreed by counsel were subsidiary.

The relationship between GGHB, the Tennent Institute and the University of Glasgow is complex. According to Dr Forwell, within the Tennent Institute some University staff are paid by the University and have clinical appointments, some Health Board staff are paid by the Health Board and have honorary University appointments, and some staff are paid in part by the University and in part by the Health Board; in this particular case, Dr Montgomery was paid by the GGHB and that, as Mr Hamer put it with reference to Mr Neil's evidence, is the only reason why Dr Montgomery is allowed to put his feet inside the door. Although Dr Montgomery contends in paragraph 5 of his first affidavit that it is the University Department and not GGHB which has teaching and research responsibilities in the Tennent Institute, this is disputed by Dr Rowan who states that GGHB does have research responsibilities in the Institute although he concedes that a large part of the research is, in fact, conducted by University of Glasgow staff. Dr Rowan goes on to say that the Tennent Institute offers an intellectually stimulating environment where Board and University of Glasgow staff work, sometimes in co-operation, on a variety of clinical problems.

I put it to Mr Hamer, and Mr Fysh did not disagree, that the research facility provided by the Institute is in effect a support unit common to the University and the Western Infirmary, although I accept that the emphasis on research is biased towards the University.

Dr Montgomery states that he had the original idea for the invention, not during clinical work, but while he was involved in private study at home and that the GGHB, which was his employer at the time, did not give him any duties which resulted in the invention and made no contribution in material, financial or intellectual terms to its development. He further states that he co-operated in the filing of the application under protest and on the understanding that, in the absence of any agreement between himself and GGHB as to how the invention should be exploited and any rewards shared, a joint referral would be made to the Comptroller to determine entitlement as to the rights of the invention. I do not consider, however, that this alleged agreement to a joint referral or his reluctance to agree to filing the application is

particularly relevant to the matter in dispute except to the extent that it demonstrates that Dr Montgomery has always believed that the invention belonged to him alone.

The GGHB does not challenge Dr Montgomery's account of the circumstances in which the invention was made. Although Dr Rowan alleges that Dr Montgomery used a technician at the Department to prepare a prototype of the invention, Mr Hamer accepted that Dr Montgomery made the prototype at home in the light of Dr Montgomery's denial and supporting evidence from Mr Macfarlane and Mr Irving. Thus, although it is comparatively unusual in my experience in an entitlement case, there is agreement on the circumstances in which the invention arose and the essential questions to be resolved are the nature of Dr Montgomery's normal duties and whether the circumstances were such that an invention might reasonably have been expected to result.

Although Mr Fysh accepted for the purposes of the Hearing that the onus lay with the referrer, he submitted that English law leans against employers and he invited me to approach this dispute with a liberal pre-disposition towards the employee by applying the philosophy of English law that a professional man in particular is entitled to make use of his expertise unless the law says otherwise, in other words, that I should find for Dr Montgomery unless I conclude on the balance of probabilities that the case falls within the specific exceptions of 39(1)(a) and (b) which Mr Fysh termed respectively the "employed to invent" and "the directors"' exceptions. Mr Hamer expressed concern at this approach and in particular lest I be unduly influenced by Mr Fysh's shorthand references to the sections of the Act. In the circumstances of this case, in which it is clear from the evidence that there was a dispute about ownership from the outset and that neither side had great expertise in patent matters, I do not think that it would be right for me to consider the matter from the outset with any sort of presumption in favour of either party; the Act makes it quite clear that, unless the exceptions set out in sections 39(1)(a) and (b) apply, the invention belongs to the employee by virtue of section 39(2).

Turning to the matter of Dr Montgomery's normal duties and with reference to his curriculum vitae, Mr Fysh argued that it is clear that Dr Montgomery regards his main duties as clinical and surgical work and that his research work, his teaching activities and the preparation and presentation of learned papers are secondary, and that he is not, as the GGHB would have me believe, primarily a researcher. Although from their evidence the GGHB might have thought that Dr Montgomery should be undertaking the ancillary duties, it was clear in Mr Fysh's view that, in practice, he was concerned with the clinical and surgical treatment of eye disease.

Mr Fysh conceded that the invention of the application in suit relates to a product which can be used in the ophthalmic departments of hospitals, particularly teaching hospitals like the Tennent Institute, and that it is a product within the field of Dr Montgomery's specialist professional knowledge and expertise and was devised as a result of his specialist experience. However, he went on to state "But these two facts alone do not ipso facto make it the Hospital Board's invention. The statute identifies the enquiry by reference not just to duties or experience or what a person does, but to his normal duties; the normal duties of an employee are the ordinary duties and in the context of the work the ordinary things one is required to do at work, not extraordinary things, not ancillary things -- the normal things-" and in his submission, section 39(1)(a) merely reflects the "employed to invent" employee. According to Mr Fysh I must consider not only the contract of employment but also the reality of the work which Dr Montgomery does in determining his normal duties and in support of his submission Mr Fysh drew my attention to the decision of Whitford J in Electrolux Ltd v Hudson and others [1977] FSR 312. Mr Fysh went on to refer me to the decision of Falconer J in Harris' Patent [1985] RPC 19 where it was held that:

"(1) Rights as between an employer and employee in an employee's invention made after the appointed day are governed only by the provisions of section 39.

(2) The circumstances in which the invention in suit was made, rather than those in which any invention whatsoever might have been made, were the "circumstances" referred to in paragraph (a) of section 39(1).

(3) An employee's normal duties were the actual duties which he was employed to do. His duty of fidelity to his employer was to carry out faithfully his normal duties to the best of his ability and did not assist in formulating what those duties were."

I do not consider that I need deal with these cases further, nor indeed with the case of Patchett v Sterling Engineering Co Ltd (1955) 72 RPC 50 referred to by Mr Hamer, since there was no argument between Counsel as to the law to be

applied in the present case and the circumstances of the precedent cases are unhelpful. In the Hudson case in particular, Mr Hudson was employed as a storekeeper carrying out what Mr Hamer described as effectively a purely mechanical function and although Mr Fysh might be right in his submission that Dr Montgomery was a junior person in the hospital hierarchy despite his title of Registrar, it is quite clear that Dr Montgomery is nevertheless a very distinguished and highly skilled man whose duties are far from being merely mechanical functions.

Returning to the circumstances of the present case Mr Fysh considered the role of a hospital and it was his contention that, although it may provide increasingly sophisticated diagnostic, testing and research facilities and possibly share these facilities with another institution, the essential purpose of the hospital is to treat illness and not to develop or design medical equipment. To the extent that a hospital may have a medical engineering department, Mr Fysh added, such units are supportive of the main function of the hospital and, in the present case, are attached to the University of Glasgow.

Against this background Mr Fysh moved on to consider Dr Montgomery's contract of employment (Exhibit K of Dr Montgomery's third declaration). This comprises a letter from the GGHB offering Dr Montgomery the appointment as Registrar in the Department of Ophthalmology at Western Infirmary which inter alia refers to working hours, leave and salary and, at paragraph 4(a) states that "Your duties are defined in the job description already issued". The job description which, as Mr Fysh stated, is a key document, sets out in paragraph 1 the relationship between the Western Infirmary and other hospitals and the Tennent Institute and explains that there is to be a review of eye services in Glasgow, it explains the work of the Department in paragraph 2 including the medical staffing, and in paragraph 3 it refers to "The Post" and sets out the names of the consultants. Under the main heading of "The Post" there are a number of sub-headings the first of which is entitled "Duties of the Post", in which three main areas of clinical responsibility in the out-patients, casualty and in-patient departments are specified and the hours of duty and leave are set out.

The next sub-heading is "Teaching", which explains that the appointee will be expected to participate in undergraduate and postgraduate teaching, followed by the sub-heading "Research" which states that "The Department is active in both basic and clinical research and the appointee will be expected to avail himself of the facilities provided". There are a number of other sub-headings set out dealing with administrative involvement, location of duties, study and training and so on.

In Mr Fysh's view the normal duties of the post are those identified under the sub-heading "Duties of the Post" which are medical duties and that the other activities are open to him to become involved in or avail himself of the facilities if he wishes but the research department is not his normal place of employment and, in particular, it is not his normal duty to work as a basic or clinical researcher. It is not surprising according to Mr Fysh that the job description is silent as to how Dr Montgomery might go about patenting any inventions he might make because it is not a job in which one would expect on a reasonable basis any invention to result.

Mr Fysh drew support for this argument from the evidence of Professor Foulds who states that he was partly responsible for drawing up Dr Montgomery's job description and who goes on to say in paragraph 4 of his declaration:

"In 1988 Dr Montgomery was a comparatively junior registrar in training and his duties were essentially clinical duties involving the care and treatment of patients. Inventing things was not part of his duties as a registrar and he would not have been in any way failing in his duties had he not sought to invent anything. I would not have expected any invention to have resulted from his normal duties".

This is consistent in Mr Fysh's submission with Dr Montgomery's understanding of the position. In summary Dr Montgomery states that he believed that his responsibilities as a clinical registrar were restricted to the clinical care and treatment of patients as described in his job description under the headings "Duties of the Post" and "Location of Duties". He says that he had no obligation to be involved in teaching or research, that he never considered these to be part of the duties for which he was paid his salary and that these opportunities were made "for the furthering of the career of clinical staff". He concedes, however, that he does take part in teaching activities but argues that he is paid for these activities separately from the Institute's discretionary fund and that this confirms his belief that teaching does not form part of his normal duties and by analogy, neither does research.

Dr Montgomery goes on to admit that as an aspect of his employment he was given the opportunity to avail himself of the Institute's research facilities but suggests that these facilities were provided more by the University than the GGHB.

He adds that although he made use of these research facilities, he did not do so in connection with the invention which is the subject of the application in suit. He states that his invention actually arose when, in the first half of 1988, he was preoccupied with study and revision before taking final examinations for qualification of the Royal College of Surgeons. While studying a text book shown as exhibit B he hit on the invention in dispute.

On behalf of the GGHB Mr Hamer did not dispute that the primary duty of the Registrar is to be a clinician and not to research but that, nonetheless, it is a significant part of the equation that is attractive to the employer that the potential employee has a desire and the ability to undertake research. In his view Dr Montgomery must have taken a similar view to have referred to his research interests in the curriculum vitae and the evidence of both Dr Montgomery and Professor Foulds supports the contention that an interest in research is important both in the securing of a position and promotion; indeed, in paragraph 5 of his second declaration, Professor Foulds says that the absence of an interest in taking part in teaching or research would seriously jeopardise the chances of a person being appointed and this was taken by Mr Hamer as a strong indication that research is a part of the job, otherwise the employer would discourage the clinician from using the research facilities.

It is also important, in Mr Hamer's submission, to note that Dr Montgomery's clinical work took place in a teaching hospital with particular research facilities available for the registrars concerned and of which they were expected to avail themselves. It is clear from Dr Montgomery's curriculum vitae that a number of the operations he conducted were only carried out after some visual assessment and that the invention is entirely concerned with what he was doing and the instruments he was using on a daily basis. Although Dr Montgomery disputes the evidence of Dr Skinner and Mr Fleming that their understanding was that he had made the invention in the course of his clinical work at the hospital, he nevertheless recognises in paragraph 5 of his first affidavit that it may have been stimulated by his work which, Mr Hamer argued, is a strong indication of itself that the invention belongs to the employer.

Mr Hamer went on to say that the point of the research facility is to seek improvement in the treatment and diagnostic care of patients and is indicative of the nature of the employee that is required. He drew my attention to paragraph 10 of Dr Rowan's evidence where he says that research was directed at patient care and is not merely an academic exercise and, on Mr Hamer's understanding of paragraph 6 of Professor Foulds second declaration, this is not disputed.

Turning to the general role of the doctor, Mr Hamer argued that, in assessing and treating the patient, there are many decisions to be made depending upon a range of circumstances and if he encounters a problem and recognises a way in which it can be overcome then, in the absence of other constraints, he owes it to the patient to provide the best possible service. Thus if somebody employed by the Health Board perceives a better way of doing what he is employed to do, then the Board is entitled to that invention and to use it for the patients. In essence, Mr Hamer argued, the position is no different from that of an employee who is employed to repair things who conceives an improved way of making the repair or of an employee who is employed to design products and perceives an improved design where, prima facie, the inventions would be owned by the employer.

Referring to the contract of employment and the job description, Mr Hamer contended that Dr Montgomery was not employed to operate on a mechanistic basis but as someone who was forward looking and inventive and is supposed to be an imaginative skilled addressee who is expected to spend time undertaking teaching and research connected with his main duties. He is in post as a clinician but in so far as he encounters difficulties or comes across improvements and can do something about improving his treatment, then he would be expected to do it. In Mr Hamer's submission all of the activities listed as sub-headings under the general heading of "The Post" in paragraph 3 of the job description are all duties of one sort or another and in particular he drew my attention to the sub-heading entitled "Location of Duties" which states in the second paragraph "In addition to the above duties the appointee will be liable for duty in occasional emergency and other unforeseen circumstances . . .". In Mr Hamer's interpretation, the job description of this post is still dealing with the duties expected of the Registrar and since the sub-headings concerned with teaching and research opportunities precede this reference, then it follows that they must be regarded as normal duties.

In their submissions under section 39(1)(a) both Mr Fysh and Mr Hamer adopted two approaches; first they considered what Dr Montgomery's duties were in practice and second, what his duties were having regard to his contract of employment. Both sides agreed that the matter in dispute is concerned only with Dr Montgomery's normal duties and not with any specifically assigned duties, and that his normal duties included the three areas set out under the heading "Duties of the Post" in his job description, namely clinical responsibilities in the Out-Patient Department and in Casualty and duties relating to the opthalmic and general care of patients including ophthalmic surgery.

I will consider first what Mr Fysh referred to as the reality of the situation, that is, what Dr Montgomery did in practice. There is no doubt that Dr Montgomery had a demanding schedule in discharging his clinical and surgical responsibilities and, in addition, in undertaking a certain amount of teaching. I accept Mr Fysh's argument that this would not leave Dr Montgomery with a great deal of free time to devote to research and that research and the making of inventions would not have been at the forefront of Dr Montgomery's mind during his daily routine.

Nevertheless, in carrying out what are agreed were his primary duties, I think that Mr Hamer was correct in his submission that, like any doctor, Dr Montgomery would have encountered a range of problems in dealing with his patients which he would have to try to overcome and, no doubt, he would overcome the majority of these problems by using his own considerable professional expertise, possibly with the aid of other support services in the hospital. I put it to Mr Hamer, and Mr Fysh did not dissent, that, if Dr Montgomery had difficulty with a particular piece of apparatus that was not performing satisfactorily then, in the normal course of events, the matter would be referred back to the manufacturer and the ownership of any invention which resulted from its modification, prima facie, would be with the manufacturer.

In the circumstances of the present case I am satisfied that the duties described under the heading "Duties of the Post" in his job description required Dr Montgomery to attend clinics such as visual assessment clinics where he would assess the ophthalmological status of patients using various types of optical equipment and his experience of the drawbacks of such equipment is referred to in his evidence. Thus it would appear that Dr Montgomery's normal duties included situations where he would be well aware of the problem that his invention is designed to overcome in that his duties would require him to make the ophthalmic examinations which are facilitated by his invention. Further it was conceded by Mr Fysh that the invention of the application in suit relates to a product which can be used in the ophthalmic departments of hospitals, particularly teaching hospitals like Tennent Institute, and that it is a product within the field of Dr Montgomery's specialist professional knowledge and expertise and was devised as a result of his specialist experience. In his evidence Dr Montgomery states that it was never suggested to him that he had any obligations to be involved in either teaching or research and that he never considered such activities to be part of the duties for which he was paid his salary. Nevertheless Dr Montgomery concedes that he did take part in teaching activities, although he argues that he was paid for those activities separately from the Institute's discretionary fund, and that this confirms his belief that teaching did not form part of his normal duties. In my view the evidence does not suggest that, in practice, Dr Montgomery considered it to be anything other than normal that he would undertake teaching duties and that, in a teaching hospital, that is to be expected.

With regard to the matter of research, the essence of Dr Montgomery's argument is that it is the Department of Ophthalmology of Glasgow University which provides opportunities and facilities for research rather than the GGHB and that, since the Institute recognises the value of teaching and research experience for the furthering of the career of clinical staff, it makes these opportunities available in order to attract applicants of high calibre. While I accept that persons such as Dr Montgomery will consider and attach importance to the facilities available when applying for a post at the Institute, it seems to me that Mr Hamer must be right in his submission that, in so far as the GGHB is concerned, the main reason for making the research facility available must be for the benefit of patients. While Dr Montgomery argues that research was not a part of his normal duties, and I recognise that it may not have been formally built into his timetable in the same way as his teaching activities, possibly because of his workload or possibly because of the nature of research, he admits that he did make use of the research facilities, although not in connection with the invention which is the subject of the patent in suit, and he does not deny that his access to the facilities was solely by virtue of his employment by the GGHB.

If I am right in concluding that the research facilities are provided primarily for the benefit of patients, then it seems to me to follow that Dr Montgomery would turn to the facility when the need arose either in respect of a particular patient or if he wished to investigate how more general treatments might be modified or improved. Thus, whilst research might not have been a regular feature of Dr Montgomery's work, it seems to me at the very least to be a facility to which someone in Dr Montgomery's position with responsibilities to patients would need to turn in the normal course of his work.

In so far as the reality of the situation is concerned, as Mr Fysh put it, Dr Montgomery became increasingly aware of the shortcomings of the optical device in question through his dealings with patients. He may not have felt under any obligation to make an invention to solve the problem and, in the case of a more complicated piece of apparatus, he may

well have had to refer the problem elsewhere, but clearly he felt that it was within his expertise to tackle this particular problem. Having got this far it seems to me that Dr Montgomery might well have turned to the research facilities available to test his theories but he did not do so and he hit upon the solution and built a prototype at home.

Reference was made on a number of occasions during the Hearing to the fact that Dr Montgomery made the invention at home without using the Institute facilities. For his part Mr Fysh did not argue that this should be determinative but he did submit that it is a very strong piece of evidence which I should take into account. I have no difficulty with the general proposition which Mr Fysh put to me but, in the circumstances of this case, I do not consider that the making of the invention was unconnected with Dr Montgomery's primary duties as a clinician and I have to accept Mr Hamer's argument that the precise location where the invention was made is largely irrelevant. I have difficulty in coming to any conclusion other than that, in making the invention, Dr Montgomery was carrying out his normal duties which satisfies the first test set out in section 39(1)(a).

In deference to Mr Fysh's request that I should consider what Dr Montgomery actually did as opposed to what he was supposed to do under the terms of his contract, I have deferred my consideration of the job description until this point in my decision, but I have to say that I do not consider that there is a great deal of conflict between the two.

Under the heading of "The Post" in paragraph 3 of the job description, the sub-heading "Duties of the Post", about which there is no dispute, sets out the clinical and surgical responsibilities. The other sub-headings are given equal status under the broad heading of "The Post"; the sub-headings concerned with teaching and research opportunities explain that he will be expected to teach and to avail himself of the research facilities available respectively and the further sub-heading I note in particular is concerned with location of duties and sets out where the post holder will be expected to work and when he will be expected to be on duty.

I do not believe that there could be much room for doubt in the mind of someone applying for the post in question and having read the job description that all the items identified under the various sub-headings formed part of the job and would be part of the normal duties. Indeed Dr Montgomery has not challenged the expectation that he would be required to teach, nor the requirements set out under the sub-heading location of duties and I can see no justification for singling out the expectation that he would avail himself of the research facilities as an exception to his normal duties.

I therefore find that Dr Montgomery made the invention in the course of his normal duties and I must now consider whether the second test in section 39(1)(a) is satisfied, that is whether the circumstances were such that an invention might reasonably have been expected to result.

If I can summarise Mr Fysh's arguments in this respect they were that, in general terms, the role of the hospital is the treatment of illness and not to design or develop equipment and, to the extent that a medical engineering department may exist in a hospital, then it is merely supportive of the greater work of the hospital; he did not go so far as to suggest, however, that in the research department of a teaching hospital an invention would not be likely to result. Mr Fysh went on to say that Dr Montgomery was employed not as a researcher but as a clinician and, as such, his duty is not to devise new instruments but to treat patients by the best methods available. Thus, if I understood him correctly, the proposition that Mr Fysh was putting to me was that since Dr Montgomery was not employed to invent, no invention could be expected to result from his work and so he could not be caught by what Mr Fysh termed the "employed to invent" provision of section 39(1)(a).

In reply Mr Hamer argued that this is too high a requirement and that, taken literally, an employee must be somebody who is employed as an inventor before section 39(1)(a) can bite. Mr Fysh did not take the matter further and I accept Mr Hamer's argument. Mr Hamer explained that it was not the GGHB's case that Dr Montgomery was a researcher but that he is a clinician who is expected in the normal course of his duties to try and improve upon the treatments he gives to patients and that, if that means changing an instrument for the better, then so be it.

I have already found that research was a part, albeit perhaps not a large part, of Dr Montgomery's duties. The use of research facilities implies analysis, experimentation and investigation which may be expected to lead to original ideas and to invention and, in any case, Mr Fysh did not seek to deny that an invention might reasonably be expected to result from research in a teaching hospital. Indeed there is evidence that inventions were made and that three patent applications were applied for in the name of the Board. I am therefore satisfied that the second test in section 39(1)(a) is satisfied.

In conclusion, therefore I find that the invention of the application in suit was made in the course of Dr Montgomery's normal duties in circumstances such that an invention might reasonably have been expected to result from the carrying out of those duties and, having so found, I do not need to consider the arguments put to me in connection with section 39(1)(b). Dr Montgomery fails in this reference and I decline to grant the relief which he seeks.

Both parties have asked for costs and, since I have found in favour of GGHB, I direct that the referrer, Dr Montgomery, should pay to the Greater Glasgow Health Board the sum of L1000 (one thousand pounds) by way of contribution to its costs.

On appeal the parties were represented as before.

COUNSEL:

Michael Fysh, QC appeared on behalf of the applicant; George Hamer appeared on behalf of the respondent.

PANEL: JACOB J

JUDGMENTBY-1: JACOB J

JUDGMENT-1:

JACOB J: I have before me an appeal from a decision of the Superintending Examiner dated 22 September 1994. The appeal is by a Dr Montgomery who is in dispute with his employers over the ownership of a patent for a device for examining the retina. His employers are the Greater Glasgow Health Board.

The dispute began before the patent application with which I am concerned was made. It is quite plain that both sides were in some considerable confusion as to what the legal position was. This is often the case in the world of academe or in the medical world or, as here, a mixture of both.

Agreements between universities and their employees, between hospitals and their employees, are often vague on the point. It is often unfortunate because it means that parties are unable either to make proper arrangements for the patent of an idea in the first place or arrangements at an early stage at least for the exploitation of the inventions.

Here the parties behaved in an extremely civilised manner as regards what to do about Dr Montgomery's idea. It was agreed that his employer would make the patent application and the dispute would then be resolved by the proceedings which have ended up in front of me. In that way the patent itself and any value in it has been reserved for whoever is entitled to it.

At one point Mr Fysh for Dr Montgomery raised a question of onus of proof. The application is made under section 12(1) of the Patents Act 1977 which appears to cast the onus on to anyone challenging the entitlement of an applicant. In the end nothing turned on the question of onus of proof because the facts are substantially not in dispute.

It would be unfortunate if anything had turned on the question of onus of proof because the question of who the applicant was was part of the civilised resolution of the problem between the two parties, which I have already mentioned. In other cases it may make sense that in relation to any similar dispute the parties agree that nothing will turn on the onus of proof and thereby allowing one of them to make the application and the question of entitlement to be determined later.

Turning back to this case, at the time of the invention Dr Montgomery was a junior registrar of three years' standing. He was spending nearly all his time treating patients, working a very long week. He was doing some examinations. Within the department in which he was working he was a very junior member. He expresses it thus himself, "The greatest responsibility which a registrar might expect in the institute would be to be involved with the junior staff duty rota and organisation of the Christmas party". What he was doing was, in his own words, working most of his life "treating, caring for and correcting the eyes of the people of Glasgow".

The dispute arises under section 39(1) of the Act. Section 39 reads:

"39(1). Notwithstanding anything in any rule of law an invention made by an employee shall, as between him and his employer, be taken to belong to his employer for the purposes of this Act and all other purposes if

(a) it was made in the course of the normal duties of the employee or in the course of duties falling outside his normal duties, but specifically assigned to him, and the circumstances in either case were such that an invention might reasonably be expected to result from the carrying out of his duties; or

(b) the invention was made in the course of the duties of the employee and, at the time of making the invention, because of the nature of his duties he had a special obligation to further the interests of his employer's undertaking.

(2) Any other invention made by an employee shall, as between him and his employer, be taken for those purposes to belong to the employee.

(3) Where by virtue of this section an invention belongs, as between him and his employer, to an employee, nothing done

(a) by or on behalf of the employee or any person claiming under him for the purposes of pursuing an application for a patent, or

(b) by any person for the purpose of performing or working the invention, shall be taken to infringe any copyright or design right to which, as between him and his employer, his employer is entitled in any model or document relating to the invention."

The section begins with the words, "Notwithstanding anything in any rule of law". I had some difficulty in understanding those words at first until I saw, as Falconer J pointed out in Harris' Patent [1985] RPC 19, that section 42(2) prevents any agreement derogating from the rights given to employees by the Act.

The section -- and only subsection (1)(a) matters -- raises the first question, "What are the normal duties of the employee?" (I am not concerned in this case with any duties falling outside his normal duties). So, what were the normal duties of Dr Montgomery? They appear from his contract. The actual contract of 11 November 1985 says:

"Your duties are as defined in the job description already issued."

Going to that document, one finds the duties of the post, and under that heading the description says:

"The appointee will have clinical responsibilities in the Out-Patient Department and in Casualty and will also have duties relating to the ophthalmic and general care of in-patients including ophthalmic surgery.

The hours of duty of this post are the standard working week of ten units of medical time (40 hours) and, in addition, the appointee will be available for eleven Class A UMTs (standing by or working at hospital) and nil Class B UMTs (available on call) on average each week, calculated as follows . . .".

"UMT" is National Health Service jargon for Unit of Medical Time. Mr Fysh told me that in practice Dr Montgomery was working just over 80 hours a week. What he was doing was treating patients, and that is what the duties of the post as set out in the job description are.

The job description also describes a number of other things which are not described as "duties". In relation to teaching it says:

"The appointee will be expected to participate in undergraduate and postgraduate teaching of Ophthalmology."

It then says of research opportunities:

"The Department is active in both basic and clinical research and the appointee will be expected to avail himself of the facilities provided."

The location of the duties were in the Western Infirmary and one session in Glasgow Eye Infirmary.

I think it is instructive not only to look at the formal document but to see what Dr Montgomery's head of department said about his duties. His head of department was Professor Foulds, and he says:

"As Head of Department I was partly responsible for drawing up Dr Montgomery's job description referred to in the statement, and I have known of Dr Montgomery and his responsibilities since he joined the Institute in 1985.

In 1988 Dr Montgomery was a comparatively junior registrar in training and his duties were essentially clinical duties involving the care and treatment of patients. Inventing things was not part of his duties as a registrar and he would not have been in any way failing in his duties had he not sought to invent anything. I would not have expected any invention to have resulted from his normal duties.

I know the job description included an expectation that the registrar would become involved in research and teaching. However, this was not something that he was contracted to do and was a somewhat informal invitation for him to become involved with the University side of the Institute, thereby making his career more interesting, opening up more opportunities for the future, and hopefully contributing to the University's research and teaching program."

That evidence was not cross-examined. One gets a very clear picture of what the doctor was doing. He was doing some teaching, and any professional man in his position would be taking an interest in research so far as it was possible consistent with his primary and essential function of treating patients.

Dr Montgomery made the invention in his own time, actually when he was preparing for some further examinations. He was not treating a patient. He was considering the problem of eye examination generally.

I have come to the very, very clear conclusion that when he made that invention he was not acting in the course of his normal duties as a registrar. I think the case is a plain one. I should, however, in fairness deal with the way the matter is put on behalf of the Board.

It is said that it was the doctor's duty to treat his patients and to think about treating his patients both by way of diagnosis and actual treatment. If he found a way of diagnosing better then provided it was consistent with his getting on with treating patients it was his duty immediately to use that. So it was, in effect, part of his duty to think of a better way of diagnosing patients.

The way Mr Hamer put it was to fasten on what was said in Harris' Patent [1985] RPC 19 and say that applied here. At page 35 Falconer J quoted a proposition which had been advanced. The proposition was, "If an employee makes an invention by applying his mind to problems experienced by his employer and if part of his duty is to apply his mind to those problems then that set of circumstances is within section 39(1)(a)". At page 37 Falconer J indicated that he thought the proposition was right. So, said Mr Hamer, "Here Dr Montgomery made an invention by applying his mind to problems of patients". Mr Hamer equated those problems with problems experienced by the Board. Mr Hamer said, "Part of his duty is to apply his mind to those problems ergo it was part of Dr Montgomery's duty to devise if he could new devices for diagnosis". Mr Hamer added the qualification "Provided he could still go on treating the patients and have enough time for that".

I think that argument breaks down as soon as you look at the conclusion. It leads to the conclusion that it is the duty of this doctor, and probably every other registrar in the country, to devise if he can new ways of diagnosing and treating patients, because his duty is to treat patients.

I therefore think that the Superintending Examiner, whose reasoning essentially adopted Mr Hamer's argument, was wrong in law.

I also think that he was wrong on the second limb of section 39(1)(a). This refers to the circumstances being such that an invention might reasonably be expected to result from the carrying out of the employee's duties. Falconer Jpointed

out that the circumstances referred to were not the general circumstances of employment but the particular circumstances surrounding the making of the invention. He said that at page 29. The particular circumstances in which this invention was made were nothing to do with Dr Montgomery carrying out his duties. He was at home. He was doing his exams.

I would only add that were the position otherwise I foresee considerable complications and difficulties. Doctors frequently devise new and better treatments. Some of those will involve patentable inventions. Most doctors are employed. If, just because they are employed and because the invention could be used for the purpose of their employment, the invention belongs to the employer then many doctors would be placed in a very difficult position -- "Can they publish what they have devised?", "Do they have to get their employer's permission to publish?" At present they do not. I do not see why they should in the future.

I would add also that my decision is consistent with the attitude taken by the Court of Appeal in relation to copyright in Stephenson Jordan & Harrison v MacDonald & Evans (1952) 69 RPC 10. In those days the issue as to who owned the copyright depended upon whether the work was made in the course of a person's employment (see section 5(1)(b) of the Copyright Act 1911). "Course of employment" is much the same as the "normal duties" plus "specifically assigned" duties of section 39(1). The Master of the Rolls, Lord Evershed, said at page 18:

"What then is the position in regard to the giving of lectures? My approach to this particular problem is this: prima facie I should have thought that a man, engaged on terms which include that he is called upon to compose and deliver public lectures or lectures to some specified class of persons, would in the absence of clear terms in the contract of employment to the contrary be entitled to the copyright in those lectures. That seems to me to be both just and commonsense."

I say just the same here in relation to an invention.

Denning LJ, as he then was, said at page 22 that:

"It must be remembered, however, that a man who is employed under a contract of service may sometimes perform services outside the contract. A good illustration is Byrne v Statist [1914] 1 KB 622, where a man on the regular staff of a newspaper made a translation for the newspaper in his spare time. It was held that the translation was not made under a contract of service but under a contract for services. Other instances occur when a doctor on the staff of a hospital, or a master on the staff of a school, is employed under a contract of service to give lectures or lessons orally to students. If he, for his own convenience, puts the lectures into writing, then his written work is not done under the contract of service. It is most useful as an accessory to his contracted work but it is not really part of it. The copyright is in him and not in his employers."

Likewise, Dr Montgomery's invention may be "a useful accessory to his contracted work" but it is not "really part" of it.

I allow the appeal.

DISPOSITION:

Appeal allowed.

SOLICITORS:

Maycock's; Bird & Bird.

DIBB LUPTON ALSOP

PATENT AND TRADE MARK ATTORNEYS

Fountain Precinct
Balm Green
Sheffield S1 1RZ
Direct Tel 0114 283 3492
Direct Fax 0114 273 0312
DX 708580 Sheffield 10

Your ref

Our ref MGFL/SJC/P70357WO

17 February 1998

Dr R E Dugdale
Director Clinical & Scientific Support Services
Bradford Royal Infirmary
Bradford Hospitals NHS Trust
Duckworth Lane
Bradford
BD9 6RJ

Dear Dr Dugdale

Patent for Lung Obturator

Thank you for your letter of 13 February 1998 from which I note your instructions.

I can now be more specific about the costs. The international application proposed to be filed will involve a cost of very close to £2250, depending on the cost of the formal drawings, which I will be able to be precise about in the next week or so, plus £650 if all possible countries are designated in the application. I attach a copy of the designation form and basically each cross that you place on the form costs £65, the cost of one of which is included in the £2250 mentioned above. There is a maximum cost of 11 designations on the forms so that if all boxes are crossed then the maximum extra charge is £650. On the other hand, if only two boxes are crossed, for example just Europe and the United States, then this will save £595 in designation fees (ie cost £2315 in total). However, you must appreciate that no designations can be made once the application has been filed. Accordingly, one needs to be rather speculative about the designations, making too many rather than too few.

Please let me have your instructions for the designations and give me a call if you need any further guidance.

As for the forms that require signing, please find attached herewith two Powers of Attorney for use in connection with the PCT application. The first one requires signature on behalf of Bradford Hospitals NHS Trust and the second by Mrs Sabanathan. It

DIBB LUPTON ALSOP

PATENT AND TRADE MARK ATTORNEYS

Continuation 2

Date 17 February 1998

requires signature by Mrs Sabanathan on the basis that she is an applicant for the invention for the United States, where it is a legal requirement that the applicant be the inventor or his heir if he is deceased. These are the only documents that need to be signed by someone other than myself in connection with the PCT application. If you can ask Mrs Sabanathan to sign the Power of Attorney form for return to me in due course, I would be very grateful. I need neither of these forms immediately, although if I have them when I file the application that would be helpful. Please not, each form needs signing twice.

I look forward to hearing from you.

With best regards.

Yours sincerely

Mark G F Lunt
European Patent Attorney

Enc

PS I did look into sending forms for the US application, but I have none which are appropriate to the present circumstances. I will write to our US associates asking for a correct form and will send that to you shortly.

Fountain Precinct
Balm Green
Sheffield S1 1RZ
Direct Tel 0114 283 3506
Direct Fax 0114 273 0312
DX 708580 Sheffield 10

email: sally.whittle@dla-law.co.uk

Your

Our ref SW.AVK.48158.2.P70357WO

4 October 1999

Dr R E Dugdale
Director Clinical & Scientific Support Services
Bradford Hospitals NHS Trust
Duckworth Lane
Bradford BD9 6RJ

Dear Dr Dugdale

INTERNATIONAL PATENT APPLICATION NO PCT/GB98/00652
OCCLUSION DEVICE
APPLICANT - BRADFORD HOSPITALS NHS TRUST ET AL

May I remind you that if you wish to proceed with the above application, then the National Phases of most countries that are of interest to you will need to be entered by **30 October 1999** at the latest. I enclose a copy of the countries that were designated to help you make your choice.

In view of the substantial amount of documentation that will probably need to be prepared, it would be appreciated if you could let us have your further instructions on the countries in which the various National Phases are to be pursued in good time before the due date.

With kind regards

Yours sincerely

SALLY WHITTLE
Formalities Manager

Enc

Enquiries on this matter should be made to:

Tel: 364132 Our ref: RED/SMT

Fax: Your ref:

Bradford HOSPITALS N H S TRUST

Bradford Hospitals NHS Tru
Bradford Royal Infirmary
Duckworth Lane
Bradford BD9 6RJ
West Yorkshire
01274 542200

01274 364134
fax.

8 October 1999

Mr Mark G F Lunt
European Patent Attorney
Dib Lupton Alsop
Fountain Precinct
SHEFFIELD
S1 1RZ

Dear Mark

Lung Obdurator Patent Application

Just a line to confirm the decision discussed in our recent telephone conversation that Bradford Hospitals NHS Trust will not be proceeding any further with the patent application for the Lung Obdurator.

Yours sincerely

DR BOB DUGDALE
Director of Operations, Clinical & Scientific
Support Services

MGL

DIBB LUPTON ALSOP
11 OCT 1999

CHARTER MARK

INVESTOR IN PEOPL

Fountain Precinct
Balm Green
Sheffield S1 1RZ
Direct Tel 0114 283 3492
Direct Fax 0114 273 0312
DX 708580 Sheffield 10

email: mark.lunt@dla-law.co.uk

Your ref

Our ref MGFL.AVK.P70357WO & GB

14 October 1999

Dr R E Dugdale
Director Clinical & Scientifique Support Services
Bradford Hospitals NHS Trust
Duckworth Lane
Bradford
BD9 6RJ

Dear Bob

INTERNATIONAL PATENT APPLICATION NO PCT/GB98/00652
UK PATENT APPLICATION NO 9708681.3
OCCLUSION DEVICE

Thank you for your telephone instructions of 7 October 1999 to drop the above identified International and British patent applications. We will not take any action positively to abandon them, in the unlikely event that the family of Dr Sabanathan wants to take over the applications. However we will not respond to any further communications nor take any action to keep the applications alive. As a result, the applications will in due course expire without issuing to grant. It only remains therefore to enclose a final note of fees which I attach herewith.

With kind regards and, of course, disappointment that this invention has not matured into a commercially viable product.

Yours sincerely

MARK G F LUNT
European Patent Attorney

Enc

FILE COPY

Fountain Precinct
Balm Green
Sheffield S1 1RZ
Direct Tel 0114 283 3492
Direct Fax 0114 273 0312

DX 708580 Sheffield 10

Your ref JR.PDM.

Our ref MGFL/SJC/P70357GB

Professor J Richardson
Consultant Anaesthetist
Bradford Royal Infirmary
Duckworth Lane
Bradford BD9 6RJ

8 May 1997

Dear Professor Richardson

New Patent Application - Lung Obturator
Applicant - Bradford Hospitals NHS Trust

Further to our telephone conversation last week and your letter of 2 May 1997, I am writing to record my sorrow at the sudden death of Mr Sabanathan. I was of course very sorry to hear this news and please accept my condolences and pass my sympathies to his family and colleagues. I only met Mr Sabanathan on the one occasion, and it is difficult to gain an impression of someone in such a short time. However, he came across as someone who cared sincerely for his patients and who was thoroughly proud of his invention which he expected to improve the condition of those many sufferers of emphysema.

On the matter of identifying Mr Sabanathan as the sole inventor, I must, as you will appreciate, take the instructions of my client, Bradford Hospitals NHS Trust, being the applicant for the patent. However, I am taking your letter as the Trust's instruction to identify Mr Sabanathan as the sole inventor, and, accordingly, as soon as I receive the application number accorded to the application in the next day or so, I will file the requisite form to identify Mr Sabanathan as the sole inventor.

However, I do not have his full name or home address, and I would be grateful if you could supply me with these details at your earliest convenience.

With best regards and, again, my sincere condolences.

Yours sincerely

Mark G F Lunt
European Patent Attorney

cc Dr M Smith, Medical Director
Mr D Jackson, Chief Executive Bradford Hospitals NHS Trust

Enquiries on this matter
should be made to: David Jackson

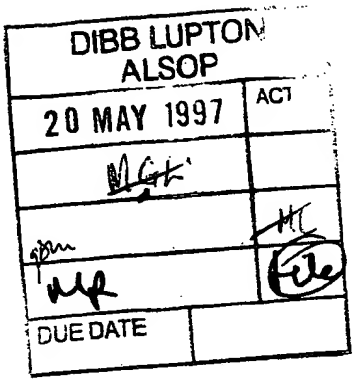
Tel: 01274 364788
Fax: 01274 364786

Our ref: DJ.DS.
Your ref:

Bradford
HOSPITALS
N H S
TRUST

Bradford Royal Infirmary
Duckworth Lane
Bradford
BD9 6RJ

Tel: (01274) 542200



18 May 1997

Mr Mark G F Lunt
European Patent Attorney
Dibb Lupton Alsop
Fountain Precinct
Balm Green
Sheffield S1 1RZ

Dear Mr Lunt

NEW PATENT APPLICATION - LUNG OBTURATOR

Thank you for sending to me copies of your letters to Professor Richardson of 8 and 13 May which were received in my office on 13 and 14 May respectively.

You need to understand that Professor Richardson is acting on behalf of the family of the late Professor Sabanathan not as the official correspondent of this Trust. As soon as possible after the Bank Holiday week, I intend to discuss the patient application with all those members of the Trust's staff who have been directly involved with the development of this invention and I think it is likely that at that stage I will identify and authorise one member of staff to act on my behalf and give instructions on the behalf of the Trust. In the meantime, as the Trust's Chief Executive, I shall act and issue instructions on behalf of the Trust which of course is the employer of the late Professor Sabanathan and all those members of staff involved in this invention.

Yours sincerely

David Jackson

DAVID JACKSON
Chief Executive

copy:

Enquiries on this matter
should be made to: David Jackson

Tel: 01274 364788
Fax: 01274 364786

Our ref: DJ.DS.
Your ref:

Bradford HOSPITALS NHS TRUST

Bradford Royal Infirmary
Duckworth Lane
Bradford
BD9 6RJ

Tel: (01274) 542200

4 June 1997

Mr Mark G F Lunt
European Patent Attorney
Dibb Lupton Alsop
Fountain Precinct
Balm Green
Sheffield S1 1RZ

Dear Mr Lunt

NEW PATENT APPLICATION - LUNG OBTURATOR

Further to my letter of 18 May, I have asked Dr R E Dugdale, Director of Operations Scientific & Clinical Support Services within this Trust, to act and issue instructions on my behalf in connection with the above. Dr Dugdale will be in touch with you over the next few days to establish the current position, what steps now need to be taken and to seek your advice generally.

Yours sincerely

David K.

DAVID JACKSON
Chief Executive

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